

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION

- - -

4 IN RE: NATIONAL : HON. DAN A.
5 PRESCRIPTION OPIATE : POLSTER
6 LITIGATION :
7 :
8 APPLIES TO ALL CASES : NO.
9 : 1:17-MD-2804
10 :
11 :

- HIGHLY CONFIDENTIAL -

SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

VOLUME II

- - -

March 8, 2019

- - -

Continued videotaped
deposition of MICHELE R. DEMPSEY, taken
pursuant to notice, was held at the law
offices of Drinker Biddle & Reath, 105
College Road East, Princeton, New Jersey,
beginning at 10:15 a.m., on the above
date, before Michelle L. Gray, a
Registered Professional Reporter,
Certified Shorthand Reporter, Certified
Realtime Reporter, and Notary Public.

- - -

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I N D E X

Testimony of:

MICHELE R. DEMPSEY

By Mr. Janush 427, 736

By Mr. Barker 579

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DEPOSITION SUPPORT INDEX

Direction to Witness Not to Answer

PAGE LINE

None.

Request for Production of Documents

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None.

Stipulations

PAGE LINE

None.

Questions Marked

PAGE LINE

None.

1 - - -

2 THE VIDEOGRAPHER: We are
3 now on the record. My name is
4 Henry Marte. I'm a videographer
5 with Golkow Litigation Services.

6 Today's date is March 8,
7 2019, and the time is 10:15 a.m.

8 This videotaped deposition
9 is being held in Princeton, New
10 Jersey, in the matter of National
11 Prescription Opiate Litigation.

12 This is Day 2 of the
13 deposition of Michele Dempsey.

14 All appearances are noted on
15 the stenographic record.

16 Will the court reporter
17 please re-administer the oath.

18 - - -

19 ... MICHELE R. DEMPSEY,
20 having been first duly sworn, was
21 examined and testified as follows:

22 - - -

23 CONTINUED EXAMINATION

24 - - -

1 BY MR. JANUSH:

2 Q. Hi, Ms. Dempsey. How are
3 you today?

4 A. Good. Thank you.

5 Q. Thank you for appearing for
6 Day 2 of your deposition.

7 When we last broke at the
8 conclusion of the January 22, first date
9 of your deposition, we were talking about
10 the audit that had been performed of
11 your -- or Janssen's suspicious order
12 monitoring system.

13 Do you remember that?

14 A. Yes.

15 Q. And I'm going to mark a new
16 document as Dempsey Exhibit 23.

17 MR. JANUSH: Copies to you,
18 your counsel.

19 (Document marked for
20 identification as Exhibit
21 Janssen-Dempsey-23.)

22 MR. BARKER: Evan, just for
23 clarification, this is a
24 collective exhibit? There are a

1 couple of documents that are
2 binder clipped.

3 MR. JANUSH: Yeah, I'm going
4 to -- I'm going to clarify that.

5 BY MR. JANUSH:

6 Q. So this is an e-mail. And
7 its Bates number is JAN-MS-0544681, and
8 it is part of a family of documents. And
9 it included, as I understand it, a
10 Janssen PowerPoint that flows
11 sequentially in Bates numbering.

12 And then following the
13 Janssen PowerPoint, is a second Bates
14 number within the family. And that Bates
15 number is JAN-MS-05444692.

16 I have added a separator
17 sheet in big bold ink to mark that
18 document with a separate Bates number.

19 And really, I just want to
20 focus on the fact that there is an e-mail
21 addressing the -- let's go to the first
22 page, if you will, at the very bottom.

23 Joshua Hankins is writing to
24 multiple people, including you,

1 Ms. Dempsey. And he's saying, "Hey,
2 team. This meeting is a follow-up to our
3 meeting on 3/19 to discuss the controlled
4 substance use case for Janssen Genius.
5 Over the next couple of weeks we are
6 going to be building and testing a model
7 for Concerta. Let me know if this time
8 works for you. Josh."

9 Do you see that?

10 A. Yes.

11 Q. Okay. And if you go forward
12 just a few pages, you'll see Janssen
13 suspicious order monitoring PowerPoint,
14 right?

15 A. JOM suspicious order
16 monitoring, yes.

17 Q. And that's Janssen at the
18 bottom --

19 A. Yes.

20 Q. -- of the -- okay.

21 And current suspicious order
22 monitoring program is being addressed.
23 And that's current as of 2018; is that
24 right?

1 A. This was at that time, yes.

2 Q. Then I'm going to flip
3 forward to that separator sheet that I
4 spoke to you about, with the big bold
5 numbers for the separate set of Bates
6 numbering.

7 And there we have the Drug
8 and Chemical Advisory Group LLC,
9 suspicious orders monitoring, SOM, for
10 Johnson & Johnson, dated December 13,
11 2017. Presented by Terrance W.
12 Woodworth.

13 Do you see that?

14 A. Yes.

15 Q. Was this the presentation or
16 the slideshow of the presentation that
17 Mr. Woodworth presented to your
18 December 13th workshop on suspicious
19 order monitoring?

20 A. Yes, it is.

21 Q. It is. Okay. And it goes
22 through an overview of drug control
23 history; is that right? Is that a yes?

24 A. Yes, yes.

1 Q. Okay. And we'll flip
2 through it fairly quickly for time
3 purposes.

4 And at Page 7, it addresses
5 U.S. drug law and regulations, Controlled
6 Substance Act, CSA, of 1970.

7 Do you see that?

8 A. Yes, I do.

9 Q. That Page 9, it's addressing
10 Schedule II through V drugs, which are
11 deemed, according to Mr. Woodworth, to
12 have a -- to include at Schedule II,
13 excuse me, hydromorphone, morphine,
14 fentanyl, methylphenidate.

15 Do you see that?

16 A. Yes, I do.

17 Q. And at Page 11,
18 Mr. Woodworth was addressing the opioid
19 epidemic in the U.S.; is that right?

20 A. Yes, he was.

21 Q. At Page 12, he was
22 addressing how in 2015 there were 52,404
23 drug-related overdose deaths; is that
24 right?

1 MR. BARKER: Object to form.

2 THE WITNESS: Yeah.

3 BY MR. JANUSH:

4 Q. And he addressed there were
5 143 deaths every 24 hours; is that also
6 right?

7 MR. BARKER: Object to form.

8 THE WITNESS: That is the
9 data that he presented.

10 BY MR. JANUSH:

11 Q. Okay. He presented data
12 that 33,091 deaths involved opioids
13 including heroin; is that also right?

14 MR. BARKER: Object to form.

15 THE WITNESS: That is what
16 is presented on the slide, yes.

17 BY MR. JANUSH:

18 Q. And he went into a little
19 bit more detail about the -- on an
20 average day in the U.S., at Page 13, the
21 650,000 opioid prescriptions that are
22 dispensed; is that right?

23 MR. BARKER: Object to form.

24 THE WITNESS: The slide does

1 present the data on the opioid
2 prescriptions, yeah.

3 BY MR. JANUSH:

4 Q. And he addressed, at Page
5 14, opioid diversion and abuse and the
6 high abuse potential of these drugs; is
7 that right?

8 A. He did speak to high abuse
9 potential during the presentation.

10 Q. And he addressed severe
11 dependence liabilities as well, didn't
12 he?

13 A. He read the bullet during
14 his presentation, yes. He did. He
15 mentioned -- so these are the bullets
16 that he read during the training.

17 Q. Okay. At Page 17, he
18 addressed 21 C.F.R. 1301.74(b); is that
19 right?

20 A. Yes.

21 Q. And that says, "The
22 registrant shall design and operate a
23 system to disclose to the registrant
24 suspicious orders of controlled

1 substances. The registrant shall inform
2 the field division office of the
3 administration in his area of suspicious
4 orders when discovered by the
5 registrant."

6 Do you see that?

7 A. Yes.

8 Q. And do you recall this being
9 presented to Johnson & Johnson?

10 A. Yes.

11 MR. BARKER: Object to form.

12 BY MR. JANUSH:

13 Q. And then he defined the
14 suspicious order monitoring regulation or
15 quoted the definition at Page 18, or
16 Slide 18. Quote, "Suspicious orders
17 include orders of unusual size, orders
18 deviating substantially from a normal
19 pattern, and orders of unusual
20 frequency."

21 Do you see that?

22 A. Yes, I do.

23 Q. Did you have an
24 understanding that this was the

1 definition of suspicious orders?

2 A. Yes, we did.

3 Q. Okay. What's the earliest
4 date that you had that understanding of
5 this definition?

6 MR. BARKER: Object to form.

7 THE WITNESS: Back to my
8 early -- when I took over the DEA
9 compliance with Noramco in 2007,
10 2008.

11 BY MR. JANUSH:

12 Q. So in or around 2007 or
13 2008, you had an understanding that the
14 definition of suspicious orders include
15 orders of unusual size, orders deviating
16 substantially from a normal pattern, and
17 orders of unusual frequency; is that
18 right?

19 A. Yes.

20 Q. We're going to move on from
21 this exhibit for a moment.

22 (Document marked for
23 identification as Exhibit
24 Janssen-Dempsey-24.)

1 BY MR. JANUSH:

2 Q. I'm going to mark a new
3 exhibit as Exhibit Dempsey -- Exhibit 24.

4 MR. JANUSH: And copies to
5 opposing counsel.

6 BY MR. JANUSH:

7 Q. This exhibit is
8 Bates-stamped JAN-MS-05444730.

9 It is an e-mail from Valerie
10 Chikwendu to Michele Dempsey. And you
11 don't actually get the date until reading
12 slightly below the first e-mail. And it
13 looks like it's June 8th, 2018. Do I
14 have that right?

15 A. Yes.

16 Q. And who is Valerie
17 Chikwendu?

18 A. She is a project manager
19 from the project management organization
20 of JOM.

21 Q. And what does it mean to be
22 a project manager?

23 A. You take on a project to
24 make sure you have the funding, the team,

1 the resources, the capital expenses to
2 deliver a project.

3 Q. Does she work within a
4 different -- a specific group? For
5 example, does she work within compliance?

6 A. No, she does not.

7 Q. She does not. So she
8 assists in getting a project funded, off
9 the ground, et cetera; is that right?

10 A. She does all the tactical
11 activity to facilitate making sure a
12 project gets done when it's supposed to
13 get done.

14 Q. Okay. And she is providing
15 you with a draft e-mail, it looks like
16 to, a Sudha, S-U-D-H-A. Who is Sudha?

17 A. I believe she's a finance
18 leader.

19 Q. Okay. And in this draft
20 e-mail, she's addressing questions that
21 Sudha raised earlier in the e-mail string
22 regarding the compliance-related
23 investment to meet DEA requirements; is
24 that right?

1 A. Can I read?

2 Q. You may.

3 A. Thank you.

4 Q. It's the second page. Turn
5 to the -- follow with me, the second page
6 of the e-mail is where I'm focusing where
7 Sudha wrote in the middle of the page to
8 John Dzurenko, Katrina Purifoy -- or
9 Purifoy, and is addressing, "Agree that
10 it is compliance related. Would like to
11 understand how this investment will meet
12 the DEA requirement. Are there other
13 programs that are doing this, i.e.,
14 within commercial? What is the
15 cap/expense split?"

16 Do you see that?

17 A. Yes, I do.

18 Q. Okay. And Valerie Chikwendu
19 is drafting a response for you and she
20 wrote on Page 1, "Michele, here's the
21 e-mail I plan to send."

22 Do you see that?

23 A. Yes, I do.

24 Q. All right. And I'm moving

1 down to the draft e-mail. She wrote,
2 "Hello, Sudha. Here are the answers to
3 your questions below. I have also cc'd
4 Michele Dempsey, director of controlled
5 substances compliance, for further
6 elaboration if needed.

7 "DEA guidelines: The DEA
8 guidelines include an expectation for us
9 to flag: Orders of unusual size, orders
10 deviating substantially from normal
11 pattern, orders of unusual frequency."

12 Do you see that?

13 A. Yes, I do.

14 Q. Okay. Now, focusing on my
15 prior question, Ms. Dempsey, that I asked
16 just moments ago, I asked if you agreed
17 with that definition. And if -- you said
18 you did, right?

19 A. Yes.

20 Q. I asked when is your
21 earlier -- earliest understanding of that
22 definition, and you said around 2007,
23 2008 when you joined Noramco; is that
24 right?

1 A. Yes.

2 Q. Okay. Next sentence in this
3 draft e-mail is, "We currently have a
4 process to flag unusual based on List 1
5 chemicals, and it is not up to current
6 industry practice. The other two
7 requirements are vulnerabilities that
8 must be addressed. Our current
9 monitoring program flags orders of
10 unusual size (a running average of past
11 orders is taken and we flag any order
12 that is 300 percent more than average).
13 We do not currently account for ordering
14 frequency or cumulative effect of
15 multiple orders in one month against the
16 threshold, and we plan to incorporate
17 other ordering deviations based on
18 patterns which will be defined as part of
19 this project."

20 Did I read that correctly?

21 A. You did.

22 Q. Do you agree that at that
23 time, the we, Johnson & Johnson, or JOM,
24 did not account with its current

1 monitoring system, for ordering frequency
2 or cumulative effect of multiple orders
3 in one month against a threshold?

4 A. No.

5 Q. You don't agree or you do
6 agree?

7 A. I do not agree. The
8 algorithm, which is what is being spoken
9 to, because we're asking for capital
10 funding to reprogram, to come up with an
11 algorithm that factors in the three, the
12 current one was only looking at the
13 12-month rolling average of a quantity.

14 But our program, the
15 outside, the overall review and
16 investigation, that's where we have the
17 frequency and pattern reviewed, because
18 if a customer orders one SKU every
19 12 months, it's going to be flagged. And
20 then we look at the ordering pattern,
21 their history, and that's how -- so this
22 was for a capital appropriation to get
23 funding for an IT system.

24 Q. Let's go back to what this

1 says, because -- because you had an
2 opportunity to edit this document, right?
3 Let's go up to the top of the e-mail.

4 A. Yes.

5 Q. It says -- I'm going to
6 circle it.

7 "Made some tweaks below.
8 Thank you."

9 Do you see that?

10 A. Yes. Yes.

11 Q. Your tweaks are embedded in
12 this document, correct, in this e-mail?
13 "Made some tweaks below"?

14 A. Yes.

15 MR. BARKER: Object to form.

16 BY MR. JANUSH:

17 Q. Is that right?

18 A. I did make some
19 modifications below.

20 Q. Okay. Okay. And you didn't
21 edit the language, "We currently have a
22 process to flag unusual based on List 1
23 chemicals and is not up to current
24 industry practice."

1 You didn't edit that
2 sentence, right?

3 A. No, I -- I don't have her
4 previous one to see what she originally
5 wrote to see what I actually tweaked.

6 Q. But you didn't change it?

7 A. No.

8 Q. That language is in here,
9 you didn't modify that beyond the
10 statement that's written here, correct?

11 A. Right. Our algorithm --

12 Q. No, that's not what I'm
13 asking you. I'm -- don't talk about your
14 algorithm. I'm asking about whether you
15 modified that first sentence, beyond
16 what's written here?

17 A. No, I didn't.

18 MR. BARKER: Object to form.

19 BY MR. JANUSH:

20 Q. No, you did not, right?

21 A. No, I not modify it.

22 Q. Second sentence, "The other
23 two requirements are vulnerabilities that
24 must be addressed."

1 You didn't modify that
2 sentence beyond the language that's
3 written there, correct?

4 MR. BARKER: Object to form.

5 THE WITNESS: No, I didn't.

6 BY MR. JANUSH:

7 Q. Third sentence, "Our current
8 monitoring program flags orders of
9 unusual size, a running average of past
10 orders is taken, and we flag any order
11 that is 300 percent more than average."

12 You didn't modify that
13 sentence beyond what's written there,
14 right?

15 A. No, I didn't.

16 Q. Next sentence, "We do not
17 currently account for ordering frequency
18 or cumulative effect of multiple orders
19 in one month against a threshold, and we
20 plan to incorporate other ordering
21 deviations based on patterns which will
22 be defined as part of the project."

23 You didn't edit this
24 sentence beyond what is written here; is

1 that right?

2 MR. BARKER: Object to form.

3 THE WITNESS: I don't have
4 the original to see what I
5 actually tweaked. But this is the
6 end product which would include
7 what I tweaked.

8 BY MR. JANUSH:

9 Q. Thank you. Now, to go back
10 to what you were addressing earlier, I
11 think. Your algorithm was designed to
12 flag any order that is 300 percent more
13 than the average rolling annual weekly
14 order; is that right?

15 A. For every customer that
16 places an order for one particular SKU,
17 it looks at the 52-week history ordering
18 and compares -- takes an average, times
19 by the 300 percent, and compares the
20 current order against what they have
21 ordered -- this threshold.

22 Q. And by this threshold, you
23 mean the 300 percent more than their
24 average; is that right?

1 A. Yes.

2 Q. I'm going to move on to
3 another document that I'm marking as
4 Dempsey Exhibit 25.

5 (Document marked for
6 identification as Exhibit
7 Janssen-Dempsey-25.)

8 MR. JANUSH: Let me hand all
9 three to you.

10 BY MR. JANUSH:

11 Q. This document is
12 Bates-stamped in the upper right corner
13 vertically, JAN-MS-02960650. It's a
14 completed questionnaire from Miami-Luken
15 concerning the JOM SOM program
16 questionnaire.

17 Does that look right to you
18 on the first page, that this would have
19 been the JOM program -- SOM program
20 questionnaire?

21 MR. BARKER: Object to form.

22 THE WITNESS: It appears to
23 be the April 2014 questionnaire.

24

1 BY MR. JANUSH:

2 Q. Okay. And I've only
3 encompassed this large 70-page document
4 for your review because it included a
5 letter from the DEA way at the end of
6 this, at Bates number ending in 712. So
7 I'm going to ask you to turn to -- look
8 in the upper right corner and turn to
9 712.

10 You are with me on 712. The
11 header is -- the letterhead is from the
12 United States Department of Justice Drug
13 Enforcement Administration.

14 Do you see that?

15 A. Mm-hmm.

16 Q. The date is December 27,
17 2007.

18 Do you see that?

19 A. Mm-hmm.

20 Q. And it's signed by, if you
21 turn to Page 2, Joseph T. Rannazzisi,
22 deputy assistant administrator, office of
23 diversion control.

24 Do you see that?

1 A. Yes, I do.

2 Q. Okay. So I'm producing you
3 with the letter that was produced from
4 Miami-Luken as part of their
5 questionnaire response on your suspicious
6 order monitoring questionnaire because
7 I'm representing to you today that we
8 couldn't locate the Johnson & Johnson,
9 JOM, Noramco, or Ortho-McNeil letter that
10 might have been sent by the -- that would
11 have been sent, excuse me, by the United
12 States Department of Justice.

13 I'm going to read you the
14 first sentence. It says, "Dear
15 Registrant, this letter is being sent to
16 every entity in the United States
17 registered with the Drug Enforcement
18 Administration, DEA, to manufacture or
19 distribute controlled substances. The
20 purpose of this letter is to reiterate
21 the responsibilities of controlled
22 substance manufacturers and distributors
23 to inform DEA of suspicious orders in
24 accordance with 21 C.F.R. 1301.74(b)."

1 Do you see that?

2 MR. BARKER: Object to form.

3 Object to the preamble.

4 THE WITNESS: Yes, I do see
5 it.

6 BY MR. JANUSH:

7 Q. And in December of 2007,
8 Janssen was a manufacturer of controlled
9 substances, correct?

10 A. Yes.

11 Q. And go on to read the next
12 paragraph. "In addition to and not in
13 lieu of the general requirement under 21
14 U.S.C. 823, that manufacturers and
15 distributors maintain effective controls
16 against diversion, DEA regulations
17 require all manufacturers and
18 distributors to report suspicious orders
19 of controlled substances."

20 Did I read that right?

21 MR. BARKER: Object to form.

22 THE WITNESS: Yes, you did.

23 BY MR. JANUSH:

24 Q. Okay. Title 21 C.F.R.

1 1301.74(b) specifically requires that a
2 registrant design and operate a system to
3 disclose to the registrant suspicious
4 orders of controlled substances."

5 Did I read that correctly?

6 MR. BARKER: Object to form.

7 THE WITNESS: Yes.

8 BY MR. JANUSH:

9 Q. Okay. I'm going to have
10 you, for the purposes of time, jump down
11 to the very last paragraph on the page
12 with me. Okay.

13 It begins with, "The
14 regulation." Are you there?

15 A. Yes.

16 Q. Okay. I'm going to read it
17 out loud.

18 "The regulation specifically
19 states that suspicious orders include
20 orders of an unusual size, orders
21 deviating substantially from a normal
22 pattern, and orders of an unusual
23 frequency."

24 Do you see that?

1 A. Yes.

2 MR. BARKER: Object to form.

3 BY MR. JANUSH:

4 Q. And that's the same language
5 that Terrance Woodworth presented to you
6 on December 13, 2017, in his suspicious
7 order monitoring workshop, right?

8 A. Very similar wording.

9 Q. Okay. And it's the same
10 language that, in the e-mail below, in
11 the e-mail that we just marked into
12 evidence at Exhibit 24 that I
13 highlighted -- we'll pull that up on the
14 screen for you. It's the same language
15 that is listed in this June 8, 2018,
16 e-mail that you had the opportunity to
17 edit concerning, "The DEA guidelines
18 include an expectation for us to flag
19 orders of unusual size, orders deviating
20 substantially from normal pattern, orders
21 of unusual frequency."

22 Is that right?

23 A. Yes.

24 Q. Same language?

1 A. Yes.

2 Q. So the requirements that
3 Joseph Rannazzisi, as the deputy
4 assistant administrator, office of
5 diversion control, was listing in 2007
6 are the same requirements that you and
7 your company were acknowledging in
8 June 2018 that you had only met one of
9 the three requirements with your
10 algorithm, correct?

11 A. Our algorithm was only
12 addressing the quantity. But our program
13 outside the algorithm covered the other
14 aspects. But we wanted --

15 MR. JANUSH: Move to strike.

16 Nonresponsive.

17 BY MR. JANUSH:

18 Q. I didn't ask about your
19 program. For the moment, I asked only
20 about your algorithm. So --

21 A. But the regulation doesn't
22 say the algorithm has to have all three.
23 It just says that you have to have a
24 system.

1 Q. Right. I asked about your
2 algorithm, did I not?

3 A. Yes.

4 Q. Okay. And there's a reason
5 for me asking that. I'm going to connect
6 the dots in a moment. Okay?

7 A. Okay.

8 Q. So my question was, you were
9 acknowledging in that e-mail, Exhibit 24,
10 that your algorithm only addressed one of
11 the three requirements stated by the DEA
12 concerning unusual size, deviating
13 substantially from a normal pattern, and
14 orders of an unusual frequency; is that
15 right?

16 MR. BARKER: Object to form.
17 BY MR. JANUSH:

18 Q. I'm only speaking of the
19 algorithm.

20 A. That is what I -- what is
21 written.

22 Q. Okay. And in realtime, in
23 practice, when an order is placed for a
24 Schedule II drug, it is your algorithm

1 that will flag whether the order is
2 suspicious or atypical and needing review
3 in that moment; isn't that right?

4 MR. BARKER: Object to form.

5 THE WITNESS: When an order
6 is placed and the quantity doesn't
7 match what the weekly average of a
8 52 weeks times three, it gets
9 flagged.

10 BY MR. JANUSH:

11 Q. Right. So going back to the
12 question I asked you. In realtime, in
13 practice, when an order is placed for a
14 Schedule II drug, it is your algorithm
15 that will flag whether the order is
16 suspicious or atypical and needing review
17 in that moment, true or false?

18 A. True.

19 Q. Okay. So the fact that you
20 have a program that has the capability to
21 analyze orders beyond the algorithm only
22 comes into play when that -- on that date
23 the order is placed when an order is
24 flagged; isn't that right?

1 MR. BARKER: Object to form.

2 THE WITNESS: When the order
3 is flagged as atypical, it gets
4 investigated. And then that
5 includes running all of the
6 historical -- looking through the
7 ordering pattern, as well as the
8 frequency part of that.

9 BY MR. JANUSH:

10 Q. But you can't do an
11 investigation until the order is flagged,
12 right, in realtime?

13 A. Agreed.

14 Q. Okay. When we concluded the
15 deposition -- when we concluded your
16 first day of this deposition, we ended
17 discussing the audit and that
18 December 13, 2017, workshop by the drug
19 and chemical advisory group, as we
20 discussed earlier, right?

21 A. Yes.

22 (Document marked for
23 identification as Exhibit
24 Janssen-Dempsey-26.)

1 BY MR. JANUSH:

2 Q. Here's Exhibit 26.

3 MR. JANUSH: There are
4 copies for counsel.

5 BY MR. JANUSH:

6 Q. This has been produced by
7 your counsel following the January 21 --
8 22, excuse me, 2019, Day 1 of your
9 deposition.

10 And this document appears to
11 be the draft presented to Johnson &
12 Johnson by Terrance Woodworth dated
13 January 8, 2018; is that right?

14 A. Yes.

15 Q. And the purpose of this is
16 found within the title. It's an
17 evaluation of the suspicious orders
18 monitoring system for Johnson & Johnson;
19 is that right?

20 A. Yes.

21 Q. Okay. And Terrance met with
22 you and key customer service personnel at
23 the Piscataway facility concerning their
24 roles in the operation of the JOM

1 suspicious order monitoring program in
2 order to conduct his examination of your
3 system, his audit of your system; is that
4 right?

5 A. He met with several groups
6 to discuss the current process, yes.

7 Q. Okay. And for the record,
8 if I didn't already say this, this
9 document starts at JAN-MS-05444748.

10 I'm going to have you jump
11 to Page 3. We're just going to focus on
12 some key aspects of this document. At
13 Paragraph 3 at the bottom of the page,
14 Terrance wrote, "Start resolving the
15 issue of possibly not applying the SOM
16 order quantity assessment algorithm (SOM
17 algorithm) to all customer orders for
18 Schedule III and IV controlled substances
19 which are received via electronic data
20 interchange (EDI) throughout the day and
21 night.

22 "The SOM algorithm is run
23 against all existing controlled
24 substances orders each day at 3:45 p.m.

1 Any orders that are received by J&J
2 customer service via EDI after that time
3 may be shipped to a customer the
4 following day without being subjected to
5 the SOM algorithm unless the EDI orders
6 are checked the next morning to ensure
7 the SOM algorithm has been applied."

8 Do you see that?

9 A. Yes.

10 Q. And we addressed that, you
11 may recall, at Day 1 of your deposition,
12 this issue of -- the fact that your
13 monitoring system physically cuts off at
14 a certain point in the afternoon and
15 would require manual review the next
16 morning to ensure that controlled
17 substance orders do not go out unchecked.

18 Do you remember that?

19 MR. BARKER: Object to form.

20 THE WITNESS: Yes.

21 BY MR. JANUSH:

22 Q. Okay. This issue, was it
23 new to you following the audit or did you
24 know about this limitation, this time

1 limitation concerning when the system
2 would shut down in the late afternoon?

3 MR. BARKER: Object to form.

4 THE WITNESS: We knew that
5 the program ran every day in the
6 afternoon. And that's why it was
7 important -- when orders are
8 received, they get manually
9 entered and placed in business
10 manager hold until this program is
11 run.

12 And then the morning, the
13 timestamp for every order is
14 compared to make sure that the
15 order is placed before the report
16 is run.

17 BY MR. JANUSH:

18 Q. And then I'm going to jump
19 down to Paragraph 7. It says, "Consider
20 modifying" -- same page, same page,
21 sorry.

22 "Consider modifying
23 Janssen's corporate policy to include the
24 organization's responsibility for

1 safeguarding controlled substances and
2 preventing their diversion, maintenance
3 of effective controls to prevent
4 diversion, Title 21 United States Code
5 Section 823, and include a summary of the
6 SOM program."

7 Do you see that?

8 A. Mm-hmm.

9 Q. Who -- what was being
10 referred to here concerning modifying --
11 consider modifying Janssen's corporate
12 policy to include the organization's
13 responsibility for safeguarding
14 controlled substances and preventing
15 their diversion?

16 A. A lot of the manufacturing
17 sites had a diversion control policy.
18 And they wanted to make sure that that
19 diversion control policy incorporated the
20 suspicious order monitoring requirements.

21 Q. Okay. And at Page 8,
22 Paragraph 8, he noted, "Stop using the
23 term 'suspicious' or 'unusual' in all
24 standard operating procedures and work

1 instructions related to the corporation's
2 SOM program and start using another term
3 which is more appropriate" -- "a more
4 appropriate characterization of the order
5 evaluation possess, such as 'questionable
6 orders' or 'atypical orders' or 'orders
7 of concern.'"

8 Do you see that?

9 A. Yes, I do.

10 Q. And after receiving his
11 guidance, you all actually did stop using
12 the term "suspicious" and modified, your
13 standard operating procedures, to
14 language such as "atypical orders," or
15 "questionable orders"; isn't that right?

16 A. We started to use
17 questionable orders.

18 Q. Okay. And here too in the
19 original audit, the original draft of the
20 audit, Terrance Woodworth -- I'm going to
21 circle the center. I've already
22 highlighted it -- is addressing the
23 registrant's obligation to design and
24 operate a system to disclose to the

1 registrant suspicious orders of
2 controlled substances.

3 And Terrance quoted, "The
4 registrant shall inform the field
5 division office of the administration in
6 his area of suspicious orders when
7 discovered by the registrant. Suspicious
8 orders include orders of unusual size,
9 orders deviating substantially from a
10 normal pattern, and orders of unusual
11 frequency."

12 Do you see that?

13 A. Yes, I do.

14 Q. And that's what we've been
15 discussing, those three factors; is that
16 right?

17 A. Yes.

18 Q. Okay. And then if you move
19 to Page 8, your auditor addressed, in the
20 middle of the page, second paragraph --
21 I'm going to show you on your screen
22 where I am with the big vertical line
23 that I'm highlighting, okay, vertical
24 lines.

1 "The JOM program also takes
2 advantage of the capabilities of the SAP
3 software, which enables generation of
4 several key reports that are helpful in
5 identifying questionable aspects of an
6 order or customer activity over selected
7 time periods."

8 Do you see that?

9 A. Yes, I do.

10 Q. And then it goes on to say,
11 in the second sentence, "For example,
12 among many other possible reports, the
13 system can facilitate a report of all
14 controlled substance orders where the DEA
15 registration is missing, invalid or
16 expired; all controlled substances orders
17 where there is an incomplete or
18 inaccurately completed DEA Form 222; and
19 all monitored orders for controlled
20 substances where the quantity ordered has
21 exceeded the current threshold
22 algorithm."

23 Do you see that?

24 A. Yes, I do.

1 Q. And so that means that the
2 program looks at monitored orders where
3 the quantity order exceeded the then
4 current 300 percent of an average annual
5 weekly order; is that right?

6 MR. BARKER: Object to form.

7 THE WITNESS: The algorithm
8 has the current threshold for
9 quantity ordered.

10 BY MR. JANUSH:

11 Q. So is that right what I
12 asked?

13 A. Yes.

14 Q. And then he appears to be
15 addressing, in the last paragraph, that,
16 "Currently it appears the JOM
17 distribution center in Kentucky is unable
18 to independently render a final SOM
19 determination on a given atypical order.
20 Several different company elements, such
21 as customer service, channel operations,
22 established products, supply chain
23 analysis, and quality assurance, possess
24 information and perform key functions

1 which could pertain to every controlled
2 substance order."

3 Do you see that?

4 A. Yes.

5 Q. Okay. So was he getting at
6 the point that the Kentucky distribution
7 center could not independently render a
8 final suspicious order monitoring
9 determination because several other
10 company functions like customer service
11 and channel operations had to play a role
12 in the determination of a suspicious
13 order?

14 A. I think what he was talking
15 about is, physically in Kentucky, we only
16 have the material handlers, and that all
17 of the customer service, compliance, and
18 the planners are located in New Jersey.

19 Q. I think we're on the same
20 page. That was --

21 A. Right.

22 Q. That was what I was getting
23 at with my question.

24 A. But the order -- the order

1 is not released to pick, pack, and
2 deliver until all the elements are
3 reviewed. And that releasing happens
4 in -- by customer service, not local.

5 Q. Then on Page 9, he addresses
6 recommendations. I'm not going to go
7 through every one for the purpose of
8 time.

9 I am going to start with the
10 bottom of Page 9 at Paragraph 3. He does
11 address that you have to start resolving
12 the issue of possibly not applying the
13 SOM order quantity assessment algorithm
14 to all customer orders for Schedule III
15 and IV controlled substances which are
16 received via electronic data interchange
17 throughout the day and night, right?

18 A. Yes.

19 Q. But there's actually no
20 difference between a Schedule II order
21 and a Schedule III and IV order with
22 respect to how that algorithm ran and
23 when that algorithm cut off during the
24 day; isn't that right?

1 MR. BARKER: Object to form.

2 THE WITNESS: Well, Schedule

3 IIs don't come in through EDI.

4 BY MR. JANUSH:

5 Q. Oh, right.

6 A. Schedule II have 222s that
7 have to be entered in.

8 Q. That's right. And once
9 entered in, how do they -- how do they
10 run?

11 A. Well, when you receive the
12 order, it goes into SAP and placed on
13 business manager hold until the
14 algorithm --

15 Q. Right. So the same
16 algorithm, though, applies with these
17 Schedule II as well, is what I'm getting
18 at, right?

19 A. Yes.

20 Q. And the same cutoff of that
21 algorithm, in terms of when it runs, it
22 runs for II, III, and IV, and it stops at
23 3:45 in the afternoon; is that right?

24 MR. BARKER: Object to form.

1 THE WITNESS: It runs --
2 yes, it runs every afternoon.

3 BY MR. JANUSH:

4 Q. And stops after that 3:45
5 run, correct?

6 MR. BARKER: Object to form.

7 THE WITNESS: It takes every
8 order that's been placed up until
9 the time it runs and it runs all
10 those orders through the
11 algorithm.

12 BY MR. JANUSH:

13 Q. Right. And that includes
14 Schedule II, correct?

15 A. Yes.

16 Q. Now let's go to Paragraph 4,
17 okay?

18 "Start modifying the
19 existing suspicious order monitoring
20 algorithm and/or adding algorithms to
21 include additional evaluation criteria
22 for each specific DEA basic class of
23 controlled substance handled by J&J;
24 example fentanyl, methylphenidate, and

1 tramadol."

2 Do you see that?

3 A. Yes.

4 Q. "Consider a base unit
5 measurement" -- "unit of measurement such
6 as grams of active ingredient for the SOM
7 algorithms.

8 "Consider separating J&J
9 customers into two or more groups and
10 perform different analyses of orders for
11 these different groups; e.g., largest
12 three wholesalers in one group, smaller
13 wholesalers in another group.

14 "Consider evaluating
15 customer orders for specific DEA basic
16 classes of substances against similar
17 size and geographically placed customers,
18 and perform national, regional, state,
19 and perhaps three digit zip code
20 comparisons among like-size customers."

21 Did I read that correctly?

22 A. Yes, you did.

23 Q. Before getting Terrance
24 Woodworth's audit suggestion within this

1 report concerning this Paragraph 4, had
2 you and your team previously considered
3 modifying your suspicious order
4 monitoring algorithm in the manners that
5 he suggested here?

6 A. We were in discussion about
7 these items. After -- through
8 benchmarking, in recent benchmarking, we
9 realized these are potential enhancements
10 that DEA may expect us to do.

11 Q. And let's go to Paragraph
12 4A.

13 Quote, "Stop using the
14 current single-criterion algorithm which
15 selects and holds orders from customers
16 when the quantity of an order is greater
17 than three times, 300 percent, the
18 customer's average weekly order based on
19 a rolling 12-month ordering history from
20 that customer."

21 Do you see that?

22 A. Yes, I do.

23 Q. And this is -- this report
24 was dated January --

1 A. January.

2 Q. -- of -- January 6th -- 8th,
3 excuse me, of 2018, right?

4 A. Yes.

5 Q. And a little more than a
6 year and about two weeks -- actually a
7 year and exactly two weeks later, on
8 January 22, 2019, I first deposed you.
9 And you indicated that you had not
10 stopped using the single-criterion
11 algorithm as of that date and were still
12 using the 300 percent of the customer's
13 average weekly order in J&J's suspicious
14 order monitoring algorithm; is that
15 right?

16 MR. BARKER: Object to form.

17 THE WITNESS: We are
18 currently using the algorithm
19 while the project, which you
20 already provided information on,
21 is underway.

22 BY MR. JANUSH:

23 Q. And Terrance goes on to
24 critique the current single-criterion

1 algorithm, which, by the way -- we
2 established in the last deposition, and
3 just to refresh everything for Day 2,
4 this 300 percent of the customer's
5 average weekly order based on a rolling
6 12-month order history is the algorithm
7 that existed since the inception of
8 Johnson & Johnson's suspicious order
9 monitoring program through the present
10 date, right?

11 MR. BARKER: Object to form.

12 THE WITNESS: This is the
13 algorithm that was implemented
14 late 2006.

15 BY MR. JANUSH:

16 Q. Through the present date,
17 correct?

18 A. Yes.

19 Q. Okay. And Terrance
20 Woodworth states, "This algorithm only
21 measures quantity and does not consider
22 frequency or a pattern of ordering by the
23 same customer," right?

24 A. Yes.

1 Q. And you agree with that,
2 right?

3 MR. BARKER: Object to form.

4 THE WITNESS: It focuses on
5 the ordering of one single
6 customer, yes.

7 BY MR. JANUSH:

8 Q. And that's not my question.
9 I said this algorithm only measures
10 quantity and does not consider frequency
11 or a pattern of ordering by the same
12 customer.

13 Do you agree with that?

14 A. That is what the algorithm
15 does, the quantity.

16 Q. And so you agree with that,
17 right? Yes?

18 A. Yes.

19 Q. And the algorithm compares a
20 customer's order quantity against only
21 that customer's average annual purchases,
22 right?

23 A. Yes.

24 Q. The algorithm would not

1 detect multiple customer orders during a
2 given week, right?

3 MR. BARKER: Object to form.

4 THE WITNESS: Yes.

5 BY MR. JANUSH:

6 Q. The algorithm would not
7 detect orders which consist of gradual
8 quantity increases of controlled
9 substance over time, right?

10 MR. BARKER: Object to form.

11 THE WITNESS: That is what
12 he wrote.

13 BY MR. JANUSH:

14 Q. Is that right though?

15 A. I've never seen it happen,
16 but it -- I guess it could.

17 Q. Is it right that --

18 A. He wrote that, yes. He
19 wrote that, yes.

20 Q. I'm not asking if he wrote
21 it. I'm asking if you agree with it,
22 that the algorithm would not detect
23 orders which consist of gradual quantity
24 increases of a controlled substance over

1 time.

2 A. In theory it could happen.

3 Q. What could happen?

4 A. That if they ordered tiny
5 increases over time, by averaging it out,
6 it might -- it might not show.

7 Q. Meaning the algorithm might
8 not pick it up?

9 A. Yes.

10 Q. Okay. The algorithm would
11 not detect a new customer's orders for
12 controlled substances which initially
13 commence with larger than normal
14 quantities and remain at a constant
15 level.

16 Do you agree with that?

17 MR. BARKER: Object to form.

18 THE WITNESS: The algorithm
19 only detects what the orders are.
20 However, our outside processes by
21 onboarding new customers, we look
22 at their quantity. So, if -- so
23 what number gets entered into the
24 algorithm, I question that one,

1 that, you know, would we really
2 start a customer at a high level.

3 BY MR. JANUSH:

4 Q. Well, you would go through
5 your -- your questionnaire process,
6 right?

7 A. Yes.

8 Q. And you would get on the
9 phone with the customer and ask what
10 their needs are, right?

11 A. And then we would also
12 evaluate whether that makes sense.

13 Q. Right. And if it seemed to
14 make sense to customer service to clear
15 the order, and the order started at a
16 high number, that would be the starting
17 point for that new customer, right?

18 A. But customer service doesn't
19 do the approval. It would go to the DEA
20 compliance group that would look at it
21 and question it and ask for justification
22 for that high level.

23 Q. Okay. So you -- you
24 corrected me in terms of the department

1 that would analyze it. But I'm still
2 addressing the fundamental concept. And
3 the fundamental concept that I'm
4 addressing is that DEA compliance would
5 question and speak with the customer and
6 see if they are content with the
7 explanation that the high order is
8 justified; is that correct?

9 A. Yes. And with the
10 documentation on hand, yes, that could
11 happen.

12 Q. And so once a customer
13 starts at a high, larger than normal,
14 quantity, if they remain at that constant
15 level, the algorithm wouldn't detect --
16 it wouldn't detect anything, right?

17 MR. BARKER: Object to form.

18 THE WITNESS: If they
19 consistent -- if they ordered
20 consistently that amount over
21 time. But if they had one big
22 order and they don't order for
23 12 months, the algorithm will flag
24 it. And we'll have to investigate

1 it again. Why did you not order
2 it, so --

3 MR. JANUSH: Move to strike
4 as nonresponsive.

5 BY MR. JANUSH:

6 Q. The algorithm does not
7 distinguish between controlled
8 substances, geographic areas, or similar
9 size customers; example, similar size
10 wholesaler.

11 Do you agree with that?

12 A. Our algorithm doesn't,
13 right.

14 Q. Doesn't or does?

15 A. Does not.

16 Q. I'm going to have you turn
17 to Page 14, if you will.

18 At the top, I'm looking at
19 the bullets that fall within Terrance
20 Woodworth's Paragraph 12.

21 And to be fair, we'll go to
22 13 -- Page 13. He's addressing
23 continue -- issues to continue/enhance
24 J&J's program. And multiple bullets

1 follow.

2 And so on 14, I'm looking at
3 the second bullet. "When an SOM-related
4 action against a DEA registrant is noted,
5 determine whether there is a learning
6 from that case. Determining whether it
7 involves one of J&J's customers, and if
8 so, whether the JOM suspicious order
9 monitoring algorithm identified any
10 previous atypical orders for that
11 customer and modify the algorithm
12 accordingly."

13 Do you see that?

14 A. Yes, I do.

15 Q. Okay. And the last bullet
16 addresses, "Take past order examples and
17 evaluate their circumstances, order
18 patterns, and activity against revised
19 algorithm or algorithms to determine
20 discrepancies or adjustments needed."

21 Do you see that last bullet?

22 A. Yes.

23 Q. You didn't like that much,
24 did you?

1 MR. BARKER: Object to form.

2 THE WITNESS: I don't
3 understand that. He was saying
4 that once we include his
5 enhancements, to keep looking
6 at -- he was asking us, once we
7 identify -- we fix the
8 algorithm -- not fix -- we make
9 these enhancements for quantity,
10 frequency, and pattern, he said we
11 should run past examples through
12 it.

13 And at this time we didn't
14 understand why, because the
15 algorithm, the thresholds we
16 already are setting up is based on
17 historical ordering pattern. And
18 those orders have already been
19 investigated.

20 And, you know, by sending
21 them through the new thresholds,
22 it would have confirmed we
23 shouldn't have investigated them,
24 because they were -- our current

1 algorithm was overflagging.

2 Do you know what I mean?

3 Because we were going based on
4 SKU, with these enhancements where
5 we're going on active ingredient,
6 if we were to throw all those
7 orders through the new system,
8 they would have shown that we
9 shouldn't have investigated them.

10 And --

11 BY MR. JANUSH:

12 Q. So you're saying -- saying
13 throwing orders into a more robust
14 algorithm would have shown you that you
15 shouldn't have investigated prior orders?
16 That's your position?

17 A. No.

18 Q. Okay. So let's get this
19 straight so that I can explain my
20 question.

21 A. All right.

22 Q. As of this date that he,
23 Terrance, is making his recommendations,
24 you have a one-dimensional algorithm that

1 only looks at quantity ordered over the
2 past year, correct?

3 MR. BARKER: Object to form.

4 THE WITNESS: SKU ordered
5 over the year.

6 BY MR. JANUSH:

7 Q. Right. Only looks at the
8 SKU of a given order, meaning the same
9 NDC code, the same drug at the same
10 milligram compared to that same drug at
11 the same milligram purchased over the
12 year, right?

13 A. So, yeah. So --

14 Q. And he's saying take past
15 order examples and evaluate them against
16 when you come up with whatever your new
17 future state algorithm is, isn't he?

18 A. He is saying once we
19 incorporate the enhancements and we go to
20 active ingredient, so all of
21 methylphenidate a customer orders, run
22 these past orders through it.

23 Q. And you expect less hits to
24 result under a newer program?

1 A. Yes.

2 Q. And why is that?

3 A. Because we are currently
4 over flagging a lot because if a
5 customer -- we're basing it -- I can use
6 ADHD medicines. You know, 18-milligram
7 is not commonly prescribed. So a
8 customer may only order it once a year,
9 like in September before school starts.
10 And they only order that one 18-milligram
11 once a year.

12 But 12 months prior average
13 is zero. So we're going to flag it even
14 though it makes sense, if you run the
15 investigation, you run what they've
16 ordered the past year, or we actually go
17 back two years, they see this wholesaler
18 always gets this 18-milligram before
19 school starts.

20 Q. You're only looking at the
21 outlier where a rare order or a lesser
22 ordered product is being placed. What
23 about the scenario where a Cardinal, for
24 example, is ordering a thousand cases of

1 Nucynta every few days or 600 cases of
2 Nucynta every few days in various
3 milligrams, and your old order would have
4 only been looking -- your old algorithm
5 would have only been looking at it as SKU
6 to SKU, and your new algorithm might be
7 looking at it in the cumulative as to the
8 total amount of product that is being
9 shipped, right?

10 MR. BARKER: Object to form.

11 THE WITNESS: So when we get
12 the new enhancements, the products
13 that we would use are Duragesic
14 and Concerta and Ultram that we
15 have now. That's the historical
16 orders.

17 And those products are
18 pretty consistent in the ordering
19 pattern. So by running them
20 through, we're not going to get
21 any more new hits, because for the
22 past orders for the past few
23 years, because we divested
24 Nucynta --

1 BY MR. JANUSH:

2 Q. Sure.

3 A. So it would be a very -- to
4 have customer service -- instead of
5 focusing on our current products and
6 using this new threshold to get -- we
7 are -- it would just -- it wouldn't be
8 time well spent because we already know
9 that those past orders, the customer's
10 ordered the same time, the same
11 quantities, we know the ordering history,
12 anything that's atypical that arrived
13 would have been flagged in our existing
14 program. So that is why we didn't see
15 the value at that time.

16 Q. Got it. Okay. I'm going to
17 show you an example live in a moment.

18 A. Okay.

19 Q. And we're going to go back
20 in time to see how Terrance's
21 recommendation would have impacted you
22 years ago before you divested Nucynta,
23 fair?

24 A. Sure.

1 Q. Before doing that I want to
2 go Paragraph 13.

3 MR. BARKER: Before you ask
4 that question, Evan, are you
5 representing that the highlighting
6 is in the original document.

7 MR. JANUSH: No, I am
8 absolutely not. I highlighted all
9 of this. I apologize. I can give
10 you clean copies here. But
11 everything here is something I
12 highlighted.

13 MR. BARKER: Including
14 the --

15 MR. JANUSH: Including the
16 yellow highlighting that's
17 computer highlighted by me to
18 focus your attention on it. I
19 didn't want to play hide the ball.
20 I wanted you to see exactly what I
21 was going to turn to when I
22 touched this page. I made that
23 highlight.

24

1 BY MR. JANUSH:

2 Q. So that highlight in
3 brighter gold at the bottom of Paragraph
4 13 states, "It appears that the JOM
5 suspicious order monitoring program" --
6 or "suspicious order monitoring has not
7 reported an order for controlled
8 substances as suspicious during its time
9 in operation."

10 Do you see that?

11 A. Yes, I do.

12 Q. Do you agree with that?

13 A. We have not reported a
14 suspicious order, yes.

15 Q. And when you say we have not
16 reported a suspicious order, you are
17 referring to the fact that we, JOM, or
18 Johnson & Johnson, has not reported a
19 suspicious order to the DEA; is that
20 correct?

21 A. Right, we have -- might have
22 reported investigated orders to DEA. But
23 none were deemed suspicious.

24 Q. Did you report investigated

1 orders to DEA?

2 A. We -- I recall, and I think
3 we spoke previously in 2007, when there
4 was a Cardinal distribution license
5 issue, and we saw an increased demand in
6 California. And we reached out to San
7 Francisco DEA, explained our algorithm,
8 explained that we saw an increased demand
9 in this DC because three other DCs lost
10 their license. We didn't -- we
11 investigated it. It made sense, and we
12 didn't deem it suspicious.

13 Q. And beyond that reporting,
14 did you ever report an order to the DEA?

15 A. We had informal discussions
16 with DEA asking if they wanted every
17 order we investigated. But no, none that
18 was suspicious.

19 Q. You didn't like this
20 language that I highlighted in gold in
21 your audit report, did you? And I'm
22 circling it in red. You didn't like it,
23 right?

24 MR. BARKER: Object to form.

1 THE WITNESS: I don't know
2 what -- I -- it's -- we haven't
3 done any suspicious -- we haven't
4 reported suspicious --

5 BY MR. JANUSH:

6 Q. You didn't like having the
7 language in the -- in the report and you
8 wanted it wiped out and deleted, didn't
9 you?

10 MR. BARKER: Object to form.

11 THE WITNESS: I don't
12 recall.

13 BY MR. JANUSH:

14 Q. I'll work to refresh your
15 recollection.

16 (Document marked for
17 identification as Exhibit
18 Janssen-Dempsey-27.)

19 BY MR. JANUSH:

20 Q. I'll mark Exhibit 27 a
21 document beginning with Bates
22 JAN-MS-05444648.

23 I'm going to have you turn
24 to the last page of the e-mail.

1 And this is a family
2 document, and it's attaching a new draft
3 of the same date, Drug and Chemical
4 Advisory Group, evaluation of the
5 suspicious order monitoring system audit
6 that is JAN-MS-05444650.

7 But for the moment, I'm
8 going to look at 649, the second page of
9 the e-mail.

10 I'm going to draw your
11 attention to your e-mail to Terry.

12 And you wrote, "Hello,
13 Terry. During the review last week,
14 Brian pointed out one statement that I
15 think needs to be clarified. The below
16 statement in red can be misleading.
17 Perhaps you could consider rewording?
18 Something like, 'Due to the current
19 algorithm and order investigation
20 process, there has not been any deemed
21 suspicious that would require
22 reporting.' "

23 Do you see that?

24 A. Yes, I do.

1 Q. And the sentence that you're
2 referring to is the last sentence that is
3 also being boxed by me. "It appears that
4 the JOM suspicious order monitoring has
5 not reported an order for controlled
6 substances as suspicious during its time
7 in operation."

8 Isn't that right?

9 A. Yes.

10 Q. Okay. So Terry -- Terrance
11 Woodworth wrote back to you, "Hi, Michele
12 and Brian. I hope you are both doing
13 well. I am happy to just delete this
14 sentence altogether."

15 Do you see that?

16 A. Mm-hmm.

17 Q. And he says, "It really
18 doesn't fit well with the recommendation
19 being made. What do you think? And if
20 this is okay, do you want me to send you
21 a new draft with the sentence omitted?
22 Thank you, Michele and Brian!!"

23 Do you see that?

24 A. Yes.

1 Q. Does this refresh your
2 recollection of what happened?

3 A. Yes, it does.

4 Q. And then on the first page,
5 Brian Strehlke writes back, "Hi, Terry.
6 That sounds fine to me. From our time
7 spent together in December, I took away
8 that: One, our system has been working
9 well; two, there is an identified
10 weakness with Schedule III orders that
11 come in late in the day requiring manual
12 processing to verify their non-suspicious
13 nature; three, you made recommendations
14 necessary to enhance our process to meet
15 changing regulatory expectations; four,
16 there have been no orders identified as
17 suspicious and there have been none
18 reported.

19 "Are you in agreement with
20 the above?"

21 Did I read that right?

22 A. Yes.

23 Q. Okay. Now, let's -- going
24 with Number 2, "There is an identified

1 weakness with Schedule III orders that
2 come in late in the day requiring manual
3 processing to verify their non-suspicious
4 nature."

5 We have already established
6 that that same issue can exist with
7 Schedule II orders that come in late in
8 the day as well, right?

9 MR. BARKER: Object to form.
10 BY MR. JANUSH:

11 Q. Meaning a Schedule II order
12 that comes in late in the day, regardless
13 of whether it comes in on EDI or through a
14 manual 222 documentation, still can be
15 captured -- still may not be captured by
16 the running of the suspicious order
17 monitoring algorithm late in the day,
18 right?

19 MR. BARKER: Object to form.

20 THE WITNESS: If the human
21 error -- customer service puts the
22 order on after the time.

23 BY MR. JANUSH:

24 Q. Okay. And Terrance responds

1 to Brian, doesn't he, at the top of this
2 e-mail string?

3 A. Yes, he does.

4 Q. And he says, "Hi, Brian.
5 Okay. Sentence has been deleted!"

6 Do you see that?

7 A. Mm-hmm.

8 Q. "Yes, I am in agreement with
9 all of your takeaway comments, and I
10 would add that we felt the current
11 algorithm was one-dimensional and thus
12 had some draw backs that could be
13 addressed by enhancing the algorithm."

14 Do you see that?

15 A. Yes, I do.

16 Q. Okay. Did you agree with
17 his conclusion?

18 A. That -- it just factored --
19 yes, that it was only on quantity.

20 Q. Okay. And going -- going to
21 the bottom again to Brian's e-mail. At
22 Number 3, Brian sought to confirm, "You
23 made recommendations necessary to enhance
24 our process to meet changing regulatory

1 expectations."

2 Do you see that?

3 A. Yes, I do.

4 Q. But, there were no changing
5 regulatory expectations as it concerned
6 the three factors of an algorithm that
7 we've been addressing in Joseph
8 Rannazzisi's letter of December 2007,
9 right?

10 MR. BARKER: Object to form.

11 THE WITNESS: The three
12 factors, the C.F.R., had not
13 changed; however, there were
14 changes through interaction with
15 DEA and going to conferences where
16 there were additional
17 expectations.

18 BY MR. JANUSH:

19 Q. But the three factors hadn't
20 changed, right?

21 A. No, the factors had not
22 changed.

23 Q. Okay. And if you turn to
24 page ending in 663 in the audit that's

1 attached, and you go to Paragraph 13, the
2 statement that you and Brian Strehlke
3 asked to be removed would have appeared
4 here.

5 A. I would like to correct, we
6 didn't ask it to be removed. Terry said
7 that he would be happy to delete it. And
8 even Brian said there were no orders
9 identified as suspicious and thus had
10 none reported. It was Terry that said
11 sentence has been deleted.

12 Q. Except he said, "What do you
13 think?" Which means -- if you go back to
14 the e-mail, he put the ball in your
15 court. "What do you think?"

16 Do you see that?

17 MR. BARKER: Object to form.

18 BY MR. JANUSH:

19 Q. I'm highlighting it. I'm
20 boxing it in.

21 A. Yes. But --

22 Q. And the answer was, "That
23 sounds fine to me."

24 Do you see that?

1 A. That is what Brian said,
2 yes.

3 Q. So Brian had the opportunity
4 to say, "No, don't delete it. We
5 disagree," correct?

6 A. Yes.

7 Q. And he didn't do it, right?

8 A. Yes.

9 Q. And, again, going back to
10 the deletion, it would have appeared
11 where I'm drawing this red underline at
12 the end of Paragraph 13, correct?

13 A. Yes.

14 Q. That's not all that was
15 deleted, is it?

16 MR. BARKER: Object to form.

17 THE WITNESS: No.

18 BY MR. JANUSH:

19 Q. Do you remember other stuff
20 that was deleted, other language?

21 A. As we were working through
22 the report in identifying how to actually
23 perform the enhancements, we did identify
24 some that we didn't -- we had some

1 issues -- not issues, but we didn't
2 understand why it was there.

3 Q. Okay.

4 (Document marked for
5 identification as Exhibit
6 Janssen-Dempsey-28.)

7 BY MR. JANUSH:

8 Q. I'm going to hand you what's
9 been marked as Exhibit 28.

10 MR. JANUSH: Counsel.

11 MR. BARKER: Thank you.

12 BY MR. JANUSH:

13 Q. And this is Bates-numbered
14 JAN-MS-05444781.

15 And I'm going down to your
16 e-mail, middle of the -- I'm going to
17 draw a line to make it easier for you, if
18 you want to look at the screen too. Your
19 e-mail, second half of the first page.
20 You're writing to Terry. "Some other
21 tweaks I thought I would mention for your
22 consideration."

23 Do you see that?

24 A. Yes.

1 Q. And then go down to the
2 bottom. Last sentence. "Also, in
3 thinking this one over: Take past order
4 examples and evaluate their
5 circumstances, order patterns, and" --
6 flip the page -- "activity against
7 revised algorithms to determine
8 discrepancies or adjustment needed."

9 Quote, or I should say end
10 quote.

11 And your statement that I've
12 highlighted is: "I don't think we want
13 to question release decisions after the
14 fact. We should remove this item. The
15 intent will be covered when we implement
16 867 chargeback/data analytics and
17 reviewing actions taken against DEA
18 registrants."

19 Do you see that?

20 A. Yes, I do.

21 Q. Now, I'm going to introduce
22 you -- introduce to you, Exhibit 29,
23 which is another copy of the same draft
24 audit from Terrance Woodworth and the

1 Drug and Chemical Advisory Group. The
2 Bates numbering is JAN-MS-05444783.

3 (Document marked for
4 identification as Exhibit
5 Janssen-Dempsey-29.)

6 BY MR. JANUSH:

7 Q. And I am going to draw your
8 attention to Paragraph 12. And right
9 where I'm drawing the line on the screen
10 for your benefit is where the last bullet
11 was deleted; isn't that right?

12 A. Yes.

13 Q. Did you hire Terrance
14 Woodworth to be your independent
15 suspicious order monitoring auditor or to
16 be your lackey?

17 MR. BARKER: Object to form.

18 THE WITNESS: We hired him
19 to do an audit of our program.

20 BY MR. JANUSH:

21 Q. Did you hire him to be an
22 independent auditor or to be your lackey?

23 MR. BARKER: Object to form.

24 THE WITNESS: We hired him

1 to be an auditor of our program
2 and provide us enhancements of
3 what he is currently seeing out in
4 industry.

5 BY MR. JANUSH:

6 Q. Did you expect him to work
7 independently and give his independent
8 feedback to you?

9 A. We expected him to give his
10 feedback. And that's what this audit was
11 for.

12 Q. Why did you play a role in
13 editing his audit?

14 A. Because as this was being
15 developed, there were changes happening.

16 As -- you didn't mention,
17 but the whole funding item that he
18 suggested, which might have been fine in
19 the past, but given what Senator
20 McCaskill's -- the whole group was
21 identifying, that all these
22 pharmaceutical companies providing
23 funding, we didn't think that was
24 appropriate in this document.

1 So we took his -- his
2 recommendations; however, we also looked
3 at the current environment to see.

4 MR. JANUSH: Move to strike
5 all aspects of that answer
6 concerning funding.

7 BY MR. JANUSH:

8 Q. I didn't ask about funding,
9 did I?

10 A. No, but it was an item that
11 we also asked to be changed. Just try to
12 explain, you know, that he gave his
13 recommendations; however, there were
14 different nuances happening out in the
15 environment that would require different
16 wording.

17 Q. You all weren't handcuffed
18 to abide by every recommendation in his
19 audit, right? You could have disagreed
20 with his audit concerning anything
21 related to funding and left it in, true?

22 A. This was -- this was his
23 recommendations that we consider --

24 Q. No, that's not what I'm

1 asking. You could have kept the language
2 as it was and ignored certain quoted
3 language, true or false?

4 A. True.

5 Q. And instead you actively
6 affirmatively chose to involve yourself
7 in an independent auditor's draft and
8 edit his draft, true or false?

9 MR. BARKER: Object to form.

10 THE WITNESS: True, we made
11 changes.

12 MR. JANUSH: Okay. We are
13 going to toggle now to the
14 computer HDMI hookup. And we are
15 going to mark this exhibit as
16 Exhibit 35 (sic).

17 (Document marked for
18 identification as Exhibit
19 Janssen-Dempsey-30.)

20 BY MR. JANUSH:

21 Q. It is an Excel file too
22 large to produce at this deposition, so
23 we'll pull it up on this 49-inch screen.
24 It's JAN-MS-03739863.

1 And I have filtered this
2 Excel file to just address a portion of
3 it related to your customer, Cardinal
4 Health, and to go back in time to look at
5 Nucynta sales. And at the bottom, you'll
6 see the tab, "SAP direct sales."

7 Do you see that?

8 A. Yes.

9 Q. And I'm going to draw your
10 attention to -- close to the top of the
11 screen, about four or five lines down,
12 I've highlighted it or grayed it in. It
13 is Line 6016. Or maybe that's not Line
14 6016. But it ends in column O,
15 \$322,608.96.

16 And Column N addresses
17 Nucynta tablets, 100 milligrams, 100s, 24
18 count, and 864 as the quantity number.

19 Do you see that?

20 MR. BARKER: I'm going to
21 object to form and to the line of
22 questioning because I cannot see
23 what -- I'm looking up at that
24 screen, and I can't see what

1 you're.

2 MR. JANUSH: Okay. You have
3 a right to walk up to the screen.

4 MR. BARKER: And I'm happy
5 to do that. I'm going to pass
6 behind the witness.

7 MR. JANUSH: If you'd like.
8 If you'd like. Since I have the
9 screen in front on have me, let me
10 give you this and make life easier
11 for you. Okay.

12 MR. BARKER: That's helpful.

13 MR. JANUSH: There you have
14 a monitor. Let the record reflect
15 that I've handed my monitor to
16 Mr. Barker, opposing counsel. And
17 it is approximately 24 inches from
18 him. And it appears to be a
19 20-inch wide-screen monitor.

20 MR. BARKER: Okay. I'm also
21 objecting because I don't -- I
22 don't know how this document has
23 been filtered, and I also don't
24 know what --

1 MR. JANUSH: Okay. That's
2 fine.

3 MR. BARKER: -- what
4 information is being presented and
5 its accuracy. So I object.

6 MR. JANUSH: Okay. I
7 appreciate that. I didn't create
8 the document. I didn't edit the
9 document. You're going to get the
10 document on CD-ROM. It's an exact
11 replica. It's a saved downloaded
12 file from Janssen's production.
13 Again it's JAN-MS-03739863.

14 I have done nothing but
15 filtered Column F in alphabetical
16 order so that I could just look at
17 exemplar sales to Cardinal for
18 Nucynta in a short time period,
19 just a snippet in time.

20 BY MR. JANUSH:

21 Q. Do you understand what I'm
22 getting at?

23 A. Can you go to the left so I
24 can see the time?

1 Q. Yes. I absolutely intended
2 to do so. So let me do that at Line 16.
3 So this is September 3, 2013.

4 Do you see that?

5 A. Mm-hmm.

6 Q. Okay. It was -- was that --
7 I need a verbal answers.

8 A. Yes. Yes, I see it now.
9 Thank you.

10 Q. Okay. So the sale date is
11 9/3/13. And I'm going to scroll over.
12 Nucynta tablets, 100 mg, 100s, 24-count.

13 What's 100 mg? That's
14 100 milligrams, right?

15 A. Yes.

16 Q. What does 100s mean?

17 MR. BARKER: Object to form.

18 BY MR. JANUSH:

19 Q. It means 100 pills in a
20 bottle?

21 A. Pills in a bottle.

22 Q. And 24-count means 24
23 bottles to a pack, right, to a casing?

24 A. Right.

1 Q. A case unit, right?

2 A. Yes.

3 Q. And the number to the right
4 says 864. That means 864 cases of
5 24-count bottles of 100-milligram Nucynta
6 containing 100 pills are being ordered;
7 is that right?

8 MR. BARKER: Object to form.

9 THE WITNESS: That's what it
10 says.

11 BY MR. JANUSH:

12 Q. And the pricing lists
13 \$322,608.96.

14 Do you see that?

15 MR. BARKER: Object to form.

16 THE WITNESS: I see it.

17 BY MR. JANUSH:

18 Q. Okay. And then the very
19 same -- let's see. We'll go down to the
20 next line, 6017, three days later. And
21 we'll scroll over. The same exact
22 Nucynta purchase, same SKU, same
23 100-milligram, 100s, 24-count, 96 are
24 purchased, right?

1 A. Yes.

2 MR. BARKER: Object to form.

3 BY MR. JANUSH:

4 Q. And I'm going to scroll --
5 jump down two more lines. Two more lines
6 later, on -- four days later on
7 September 10th, 2013, 624 cases of the
8 same drug are purchased for \$232,995.36.

9 Do you see that?

10 MR. BARKER: Object to form.

11 THE WITNESS: Yes, I do.

12 BY MR. JANUSH:

13 Q. All right. Let's jump down.
14 We'll go down to where I've boxed it in
15 at Line 6027. And 480 cases at
16 \$179,227.20 have been ordered, and that's
17 three days from the last order on 9/13 of
18 2013.

19 Do you see that?

20 MR. BARKER: Object to form.

21 THE WITNESS: Yes, I do.

22 BY MR. JANUSH:

23 Q. All right. Let's keep
24 going.

1 Jumping down four lines
2 about, four days later, on September 17,
3 2013, 624 cases of Nucynta 100 -- excuse
4 me. I have that wrong. That's 60. No,
5 I have it right. My apology. My eyes
6 are playing tricks.

7 Nucynta 100, 100s, 24-count,
8 624 cases, \$232,995.36.

9 Do you see that?

10 MR. BARKER: Object to form.

11 THE WITNESS: Yes, I do.

12 BY MR. JANUSH:

13 Q. And that is on
14 September 17th, right?

15 A. Yes.

16 Q. Okay. And let's go forward
17 three days later, September 20th.

18 Nucynta 100-milligram, 100s, 24-count,
19 600 cases ordered, \$224,034.

20 Do you see that?

21 MR. BARKER: Object to form.

22 THE WITNESS: Yes, I do.

23 BY MR. JANUSH:

24 Q. Okay. Earlier we talked

1 about the Rannazzisi letter.

2 A. Mm-hmm.

3 Q. We talked about the concept
4 of frequency being a component that needs
5 to be investigated as part of a
6 suspicious order monitoring program,
7 didn't we?

8 A. Mm-hmm.

9 Q. Would you agree that three
10 and four days apart, having orders like
11 this, would be a frequency issue?

12 A. No. Because as you
13 present -- you presented some evidence
14 prior that showed -- it was an e-mail
15 that showed Cardinal always places orders
16 Mondays -- two -- twice a week. So the
17 frequency of the orders there, we knew
18 that there would be ordering on those
19 days.

20 Q. Ma'am, the fact that
21 Cardinal placed orders twice a week,
22 three times a week, four times a week or
23 five times a week is irrelevant to my
24 question. I'm asking you about whether

1 your algorithm -- your algorithm didn't
2 address frequencies, right?

3 MR. BARKER: Object to form.

4 THE WITNESS: No. But these
5 orders were probably investigated.
6 Did you --

7 BY MR. JANUSH:

8 Q. An order doesn't get
9 investigated unless it's first flagged,
10 right?

11 MR. BARKER: Object to form.

12 THE WITNESS: Well, I'm just
13 looking at this date, period, and
14 how long the ER was on the market.

15 And I'm recalling that there
16 was -- there was some
17 investigations capturing the
18 demand for Cardinal Health.

19 BY MR. JANUSH:

20 Q. Okay. But an order in
21 realtime in a moment of the day is not
22 investigated, as you testified earlier
23 today, until it's first flagged, right?

24 A. Yes.

1 Q. And you can't flag frequency
2 if frequency is not part of your
3 algorithm, right?

4 MR. BARKER: Object to form.

5 THE WITNESS: Agreed.

6 BY MR. JANUSH:

7 Q. Okay.

8 MR. JANUSH: Is this is a
9 good time for a break?

10 MR. BARKER: If you need
11 one, yeah.

12 MR. JANUSH: Let's go off
13 the record.

14 THE VIDEOGRAPHER: Stand by,
15 please. The time is 11:38 a.m.
16 Going off the record.

17 MR. JANUSH: Earlier, I had
18 represented that this Excel file
19 marked at JAN-MS-03739863 was
20 Exhibit 35. I intended for it to
21 be marked as Exhibit 30. So we
22 will correct the record to reflect
23 that it is Exhibit 30.

24 MR. BARKER: That's fine.

1 MR. JANUSH: Thank you.

2 (Short break.)

3 THE VIDEOGRAPHER: We are
4 back on the record. The time is
5 12:01 p.m.

6 BY MR. JANUSH:

7 Q. Ms. Dempsey, who is
8 Stephanie Dixon?

9 A. She's the controlled
10 substance compliance manager for JOM.

11 Q. Is that the fairly new
12 position that got added quite recently?

13 A. May of last year.

14 Q. May of 2018?

15 A. Mm-hmm, yes.

16 Q. Is she -- is Stephanie Dixon
17 the only compliance manager that you have
18 had serving under you?

19 A. She doesn't report to me.
20 But JOM has had previous compliance
21 managers from the DEA perspective.

22 Q. Okay. This was the new
23 compliance role where -- where you were
24 involved in creating a job description;

1 is that right?

2 A. Yes.

3 Q. Okay. And who does she
4 report to, Stephanie Dixon?

5 A. Jose Boursin.

6 Q. How do you spell his last
7 name?

8 A. Her.

9 Q. Oh, sorry.

10 A. B-O-U-R -- I'm sorry.

11 B-O-R -- B-O-U-R-S-I-N.

12 Q. And does Jose Boursin report
13 to you?

14 A. No.

15 Q. Who does Jose Boursin report
16 to?

17 A. Liz Allison.

18 Q. Okay. And what role does
19 Jose Boursin have?

20 A. She is director of quality
21 and compliance for Deliver, or -- which
22 is logistics organization within J&J.

23 Q. Okay. And you stated who
24 Jose reports to. Can you repeat that

1 name again?

2 A. Liz Allison.

3 Q. And what role does Liz
4 Allison have?

5 A. She is the North America
6 regional leader for quality and
7 compliance for the Deliver organization.

8 Q. Okay. Were you aware of the
9 fact that on December 17, 2018, the
10 controlled substance compliance manager,
11 Stephanie Dixon, contacted the new
12 Louisville, Kentucky DEA supervisor, Ben
13 Vinson, to request guidance on suspicious
14 order monitor reporter specifications
15 from orders shipped from the Kentucky
16 distribution center?

17 A. Yes, I am aware.

18 Q. When did you become aware of
19 that?

20 A. After she engaged with him,
21 she reviewed the conversation with me.

22 Q. What -- on or about what
23 date would that be?

24 A. It was in December. I don't

1 recall the exact date. But it was in the
2 middle -- towards the middle of December,
3 end of December.

4 Q. So she engaged with Ben
5 Vinson, according to this contact date,
6 on what I'll hand you as Dempsey
7 Exhibit 31 on December 17, 2018.

8 (Document marked for
9 identification as Exhibit
10 Janssen-Dempsey-31.)

11 BY MR. JANUSH:

12 Q. The Bates number is
13 JAN-MS-05433750.

14 Have you seen this document
15 before?

16 A. Yes, I have.

17 Q. Did it get shared with you
18 internally by a colleague of yours at
19 Johnson & Johnson?

20 A. Stephanie provided me a copy
21 of this.

22 Q. Okay. And I'm going to
23 direct your attention to -- there seems
24 to be a bunch of questions and answers,

1 questions asked by Stephanie that are
2 logged in notes on Page 1 and Page 2, as
3 well as an e-mail that follows
4 documenting a conversation between
5 Stephanie Dixon and Ben Vinson.

6 Do you see that?

7 A. Yes.

8 Q. Okay. And so with respect
9 to the question and answers, at the very
10 bottom, updated on January 21, 2019, it
11 states, on January 21st -- "On 21 Jan,
12 2019, the controlled substance compliance
13 manager contacted the Louisville,
14 Kentucky Division of the Drug Enforcement
15 Agency via an e-mail to Ben Vinson as
16 requested to send the orders flagged in
17 2018 for DEA awareness and to confirm the
18 accuracy of the telephone conversation on
19 December 17, 2018."

20 Do you see that?

21 A. Yes, I do.

22 Q. Okay. And it says -- I want
23 to circle the fact that it says here,
24 "See attachment."

1 Have you seen the
2 attachment, the orders flagged in 2018?
3 Have you seen that Excel file?

4 A. Yes.

5 MR. BARKER: Objection.

6 BY MR. JANUSH:

7 Q. You have?

8 A. Yes.

9 Q. Okay.

10 MR. JANUSH: I don't know
11 that it's been produced in this
12 case.

13 I think that to the extent
14 that it hasn't, we're calling for
15 production of that Excel file.

16 MR. BARKER: Two points in
17 response to that. The first is
18 you are misinterpreting the
19 document. It's talking about on a
20 conversation on January 21.
21 There's a January 21st e-mail
22 that's attached.

23 And secondly the document
24 that you're referring to has been

1 produced.

2 MR. JANUSH: The Excel file
3 has been produced?

4 MR. BARKER: Yes, it has.

5 MR. JANUSH: So the
6 January 21 e-mail is referencing
7 JOM monitored orders.xlsx as an
8 attachment, so I wasn't
9 misrepresenting that.

10 MR. BARKER: Oh, where are
11 you looking at?

12 MR. JANUSH: On the e-mail.

13 MR. BARKER: Oh, on the
14 e-mail itself. My apologies. I
15 now -- I thought you were still
16 reading from the bottom of Page 2
17 of the -- okay.

18 MR. JANUSH: So that's the
19 attachment that I'm referring to.
20 And you're saying that has been
21 produced.

22 MR. BARKER: It has been
23 produced.

24 MR. JANUSH: Okay.

1 MR. BARKER: And this is the
2 whole document here. But that has
3 been produced.

4 MR. JANUSH: Okay. Do you
5 know if it wasn't produced as a
6 family?

7 MS. WINCKEL: It was
8 produced as a family.

9 MR. JANUSH: It was?
10 Thanks. Thanks for that
11 clarification.

12 MR. BARKER: That helps.
13 See, if you want real details,
14 you've got to talk to Emilie.

15 MR. JANUSH: All right,
16 Emilie.

17 BY MR. JANUSH:

18 Q. Okay. So the issue that I
19 wanted to address was, first of all,
20 there's obviously a host of notes,
21 questions with answers, on the first two
22 pages of this document that precede the
23 e-mail. And it's notes contained within
24 a document called a regulatory agency

1 contact report.

2 Do you see that?

3 A. Yes, I do.

4 Q. Okay. And so Stephanie
5 wrote -- appears to have written
6 questions and written what Ben's answers
7 were. Do I have that down right? Am I
8 understanding?

9 A. These were the notes of the
10 conversations that she had with Ben.

11 Q. And in order to confirm her
12 accuracy of the conversations she had
13 with Ben, she then wrote him one day
14 before you were deposed in this case on
15 January 21, 2019; is that right? I'm
16 highlighting the date sent. January 21,
17 2019, at 11:03 p.m.

18 Do you see that?

19 A. Yes.

20 Q. Did you speak with her about
21 her seeking to contact the DEA on the day
22 before or the evening before you were
23 deposed?

24 A. No.

1 Q. Okay.

2 A. But I know that the
3 discussion happened in December, and then
4 we had Christmas holidays. And then she
5 went away for a few weeks to Florida for
6 a horse show. And then this is probably
7 the earliest we can get to it. This is
8 when she was back in the office.

9 Q. So she contacted Ben Vinson,
10 the field agent for Louisville Kentucky
11 at the DEA on September --

12 A. December.

13 Q. Excuse me. On
14 December 17th, and you're saying the
15 earlier she could get back to confirming
16 her conversation with Ben Vinson was a
17 month and four days after she first spoke
18 with him, which coincidentally was the
19 evening before you were deposed in this
20 case? Is that what you're saying?

21 MR. BARKER: Object to form.

22 THE WITNESS: Based on the
23 sent date on the e-mail, it
24 appears she sent it out on Monday

1 the 29th.

2 BY MR. JANUSH:

3 Q. 21st, right?

4 A. 21st.

5 Q. Which was late in the
6 evening before you were deposed the next
7 morning by me, correct?

8 MR. BARKER: Object to form.

9 THE WITNESS: I was deposed
10 on the 22nd, correct.

11 BY MR. JANUSH:

12 Q. Okay. And the last question
13 that Stephanie asked Mr. Vinson, if you
14 turn to the last page, the last question
15 that she sought to confirm, "Question:
16 Overall when should an order be" -- "When
17 should an order be reported to
18 Louisville?

19 "Answer: DEA used to get
20 excessive purchase reports that were too
21 much information in the past.

22 Technically, reporting should occur when
23 JOM does not deem an order suspicious,
24 but it has flagged and we released it for

1 a reason except for the reasons listed in
2 the questions above that do not need to
3 be reported."

4 Do you see that?

5 A. Yes, I do.

6 Q. So JOM had not been
7 following that kind of a policy, at least
8 prior to getting this answer from Ben
9 Vinson; isn't that right? In other
10 words, stated differently, JOM was not
11 reporting orders to the DEA when it
12 didn't deem it suspicious after an
13 investigation, but flagged it, later
14 released the order; is that right?

15 MR. BARKER: Object to form.

16 THE WITNESS: This was a new
17 expectation that Ben communicated
18 to us, because we had prior
19 engagement with a different leader
20 at Kentucky, who, when we walked
21 through this process, they were
22 fine with us not reporting if we
23 had the justification.

24 BY MR. JANUSH:

1 Q. Okay. And who was that
2 leader?

3 A. It was Billy Lane.

4 Q. Billy Lane. And do you have
5 any correspondence with Billy Lane like
6 you do in an e-mail where you wrote to
7 Billy Lane and said, "When should orders
8 be reported to the DEA?" and Billy Lane
9 wrote back and said, "Don't worry. If
10 you've investigated an order and cleared
11 it on your own, you do not need to
12 release the -- and released it after
13 investigation, you do not need to report
14 it to the DEA"?

15 A. We do not have it in an
16 e-mail. It was a verbal discussion.

17 Q. Okay. And who had that --
18 who was that verbal discussion between?

19 A. It was DEA, diversion
20 investigators Jason Smith, Billy Lane,
21 with the JOM leaders at Kentucky, Michael
22 Griffith, then Mike Levitt, Brian
23 Strehlke and myself.

24 Q. And after getting such

1 important guidance from the DEA, did you,
2 Brian Strehlke, or Michael Levitt draft a
3 memorandum where you documented that
4 guidance from the DEA, that any order you
5 investigate and flag as potentially
6 suspicious does not need to be reported
7 to the DEA as per these DEA agents that
8 you have named?

9 A. We did not write a formal
10 document. We do have the record of the
11 conversation that the recorder was typing
12 at the inspection. That's the only
13 record that we have of discussing this,
14 but nothing formally sent to Louisville.

15 Q. And where is that record of
16 this discussion with DEA?

17 A. It was attached to the
18 inspection report from their visit in
19 2013.

20 Q. Okay. And is it your
21 position that that was produced in this
22 case?

23 A. I believe it was.

24 MR. BARKER: You seem to be

1 asking that of the witness. Are
2 you asking us?

3 BY MR. JANUSH:

4 Q. Do you know whether it was
5 produced in this case?

6 A. I believe it was.

7 MR. JANUSH: Do you know?

8 MR. BARKER: Yes, it was.

9 BY MR. JANUSH:

10 Q. I'm handing you what's been
11 marked as Dempsey Exhibit 32.

12 JAN-MS-03059382.

13 (Document marked for
14 identification as Exhibit
15 Janssen-Dempsey-32.)

16 BY MR. JANUSH:

17 Q. And it contains an
18 attachment at 59385 from The Analysis
19 Group.

20 When I deposed you on
21 January 22nd, 2019, you had addressed
22 that right around Christmas time, Johnson
23 & Johnson or Janssen had contracted with
24 The Analysis Group to assist in creating

1 the -- in -- on -- creating the revised
2 suspicious order monitoring system; is
3 that right?

4 MR. BARKER: Object to form.

5 THE WITNESS: No. I said in
6 December we received a statement
7 of work for IntegriChain, another
8 consultant. We've been working
9 with The Analysis Group since last
10 summer.

11 BY MR. JANUSH:

12 Q. Okay.

13 A. Two different consultants.
14 One was working on the algorithm, and one
15 was downstream customer.

16 Q. Okay. Just as an aside, for
17 purposes of this document, this -- is
18 this document -- this e-mail string dated
19 May 15, 2018, which attaches a proposal
20 for suspicious order monitoring
21 evaluation dated May 10, 2018, is this
22 the next time following your work with
23 the -- with Terrance Woodworth that you
24 sought to retain a third party to

1 evaluate suspicious order monitoring?

2 MR. BARKER: Object to form.

3 THE WITNESS: We were not
4 asking The Analysis Group to speak
5 to our existing program. We
6 engaged them to help us identify
7 enhancements to our current
8 algorithm with the thresholds.

9 BY MR. JANUSH:

10 Q. Okay. My question was, is
11 this the next time following your work
12 with Terrance Woodworth that you sought
13 to retain a third party to evaluate
14 suspicious order monitoring. And so what
15 you're saying is, you weren't hiring The
16 Analysis Group to evaluate.

17 A. Exactly.

18 Q. You were hiring The Analysis
19 Group to help you create your next
20 system; is that right?

21 A. The enhanced algorithm.
22 Yes.

23 Q. Okay. And the attached
24 document was a proposal for preliminary

1 evaluation of controlled substance
2 monitoring opportunities dated May 10,
3 2018; is that right?

4 A. That is what on the -- yes,
5 that's what it says.

6 Q. Did this document get
7 executed?

8 MR. BARKER: Object to form.

9 BY MR. JANUSH:

10 Q. I don't see an execution
11 sheet. Did you enter into a -- into a --

12 A. We did.

13 Q. -- an agreement following
14 this?

15 A. We did, but I don't know if
16 this is the actual one, because it might
17 have been -- there's been revisions to it
18 to include the new product. And I don't
19 know if -- I didn't get to read this, to
20 see if it's in here.

21 Q. Do you know what the latest
22 date of the contract is --

23 A. Yes.

24 Q. -- with The Analysis Group?

1 A. No, I don't. Like I said
2 this is the project team that's managing
3 this. I'm a high level watching it.

4 Q. And who manages the
5 product --

6 A. Valerie.

7 Q. -- project team?
8 Valerie Chikwendu?

9 A. Mm-hmm.

10 Q. And --

11 A. I do know there's been a few
12 since then. This was the initial
13 kickoff, and more followed as we got to
14 the threshold.

15 Q. So when did you start
16 working with The Analysis Group? Was it
17 in May after receiving this, in May of
18 2018, after receiving this proposal?

19 A. I believe we had them -- we
20 had a workshop where they came in, and I
21 can't remember what day it was.

22 Q. Do you have notes from that
23 workshop?

24 A. It wasn't my -- I just

1 attended it. I didn't lead the workshop.
2 But I think it was July.

3 But yeah, so this is when we
4 were initially engaging them and getting
5 the funding to pay for them to come to
6 the workshop.

7 Q. Incidentally, does Terrance
8 Woodworth and his company also assist in
9 creating revised algorithms?

10 A. I don't know.

11 Q. Did you ever investigate
12 that with Terrance Woodworth?

13 A. No.

14 Q. No. Why not?

15 A. I just -- we --

16 Q. In other words, what made
17 you walk away from working with Terrance
18 Woodworth and move towards working with
19 The Analysis Group?

20 MR. BARKER: Object to form.

21 THE WITNESS: Oh, at a -- at
22 an HDA conference, The Analysis
23 Group was there. And they
24 introduced themselves. And I saw

1 what they provide, the services.
2 And we thought they were more
3 relevant to the actual -- doing
4 the statistical analysis.

5 BY MR. JANUSH:

6 Q. Thought what was more
7 relevant?

8 A. What they do, the services
9 that they provide, is more in line with
10 what we needed for the thresholds. I was
11 not aware that Terry could provide those
12 services. So we didn't even think to ask
13 Terry.

14 Q. When you say the services
15 that they provide, can you elaborate on
16 that?

17 A. The Analysis Group aids
18 companies with looking at their data to
19 set up thresholds for suspicious order
20 monitoring.

21 Q. Okay. But lots of companies
22 do that. How did they do it differently
23 than other companies? You were
24 explaining that there was something

1 different about The Analysis Group.

2 A. Well, you were asking me to
3 compare to Terry.

4 Q. Right.

5 A. And I wasn't -- I had not
6 heard of anything that Terry -- the
7 services that Terry provides.

8 Q. You said, "And we thought
9 they were more relevant to the actual --
10 doing the statistical analysis." And I
11 said, "What was more relevant?"

12 I'm trying to dig a little
13 deeper and find out what was it that was
14 more relevant that The Analysis Group
15 could provide you with.

16 MR. BARKER: Object to form.

17 THE WITNESS: Well, your
18 question is, why didn't we use
19 Terry.

20 BY MR. JANUSH:

21 Q. That's not my question now.

22 A. I'm sorry. Okay. Well,
23 when we engaged with The Analysis Group,
24 what services they communicated to us

1 appeared to support the enhancements that
2 we wanted to make with our program
3 because --

4 Q. And what services were
5 those?

6 A. -- they --

7 MR. BARKER: Let's slow this
8 down. Let her finish her answer
9 before we start with the next
10 question, please. Thank you.

11 THE WITNESS: So when we
12 engaged with them, they told us
13 that they come into companies that
14 distribute controlled substances.
15 They can assist them in
16 configuring their own systems with
17 threshold algorithms, or they
18 could provide -- or they can
19 provide guidance on other systems
20 that could do these calculations.
21 So they do the statistics based on
22 historical data and help the
23 companies configure their IT
24 systems to do the own threshold

1 analysis.

2 And that's what we basically
3 needed. We needed somebody to
4 help us take our historical data
5 and determine what statistics does
6 DEA expect to see on that data and
7 set up thresholds for our
8 products.

9 BY MR. JANUSH:

10 Q. What are the statistics that
11 you believe DEA expects to see to set up
12 thresholds on your products?

13 A. They expect us to be
14 monitoring quantity, frequency, and
15 patterns. And The Analysis Group has had
16 experience with other companies
17 identifying what kind of thresholds are
18 needed to address those factors.

19 Q. And again, the expectation
20 from the DEA concerning the requirement
21 that a registrant monitor quantity,
22 frequency, and patterns is not new,
23 right?

24 A. No. But we were currently

1 doing it from an algorithm and then the
2 manual for the pattern and frequency.
3 And we wanted one system that would do it
4 all automatically.

5 Q. You're not testifying today
6 that you were in realtime every day when
7 an order was being placed doing an
8 investigation of every order for pattern
9 and frequency unless an order was first
10 flagged by your algorithm, right?

11 MR. BARKER: Object to form.

12 THE WITNESS: There are --
13 obviously the orders that are
14 flagged do get the investigation.

15 But we know the typical
16 ordering pattern of the customers,
17 if they order either once a week
18 or -- the big three, or twice a
19 week. So the customer service
20 knows the typical ordering
21 patterns, that if they saw
22 somebody order twice, that they
23 would question it.

24 So that's what I'm saying,

1 the human element was trying to
2 follow the frequency and pattern.
3 And we just wanted to make the
4 algorithm do all of it at once,
5 versus relying on a manual.

6 BY MR. JANUSH:

7 Q. Except for Cardinal, where I
8 showed you on that spreadsheet, was
9 ordering three days apart from the prior
10 order for the same drug, that's not
11 something that would be flagged by your
12 algorithm, correct? And it's something
13 that you knew happened because you knew
14 Cardinal's ordering schedule, right?

15 MS. BOODY: Object to form.

16 THE WITNESS: We knew that
17 they ordered Mondays and
18 Wednesdays for example. The
19 quantity, we knew that that
20 location was the main hub that
21 Cardinal supplied all of their DCs
22 and pharmacies. So -- and that
23 quantity was obviously less than
24 the threshold unless it was

1 flagged as atypical. So...

2 BY MR. JANUSH:

3 Q. I'm going to move on to what
4 I've marked as Exhibit 33.

5 (Document marked for
6 identification as Exhibit
7 Janssen-Dempsey-33.)

8 BY MR. JANUSH:

9 Q. This looks like the
10 preliminary algorithm for --

11 MR. JANUSH: I have two
12 copies to share.

13 MR. BARKER: How many pages
14 should this be?

15 MR. JANUSH: It begins on
16 JAN-MS-05444640. And that is Page
17 1.

18 And it ends on Page 7,
19 JAN-MS-05444646.

20 MR. BARKER: One of the
21 copies you handed me goes that
22 far. The other one only has six
23 pages, going through 45. But I do
24 appear to have --

1 MR. JANUSH: Here you go.

2 There's a corrected one.

3 MR. BARKER: Thanks. You
4 want that back. There you go.

5 MR. JANUSH: And that
6 explains my problem. If you can
7 give that to Cardinal's counsel.

8 MR. BARKER: Well, that
9 should be a complete copy.

10 MS. WINCKEL: I can look on
11 here.

12 BY MR. JANUSH:

13 Q. And this is dated
14 preliminary draft February 1st, 2019.

15 Do you see that?

16 A. Yes.

17 Q. Have you seen this before?
18 This is titled "Preliminary Algorithm
19 Logic For Suspicious Order Monitoring"?

20 A. I have not seen this before.

21 Q. Okay. So I'm going to
22 represent that this was not produced with
23 any family, it was just produced
24 generally. But since you have not seen

1 it before, I'll just ask you to take a
2 look at it and ask if you can explain it.
3 And if the answer -- your answer will
4 dictate what we do next.

5 MR. BARKER: Object to form.
6 You're asking her to explain
7 a document that she's never seen
8 before.

9 THE WITNESS: Yes, this is
10 trying to explain how SAP is going
11 to work in --

12 BY MR. JANUSH:

13 Q. Are you involved in the new
14 algorithm logic for suspicious order
15 monitoring?

16 A. I am not involved in the
17 tactical execution, no.

18 Q. Okay. Who are the folks
19 that are involved in the tactical
20 execution going forward?

21 A. Stephanie Dixon. She -- the
22 control substance compliance manager.
23 IT.

24 Q. Who from IT?

1 A. Deb Sniscak. She's the
2 interface between business and IT. And I
3 don't remember the IT team.

4 Q. Is Valerie Chikwendu at all
5 involved in this project?

6 A. She's the project manager,
7 so she has the oversight of how the
8 activities are progressing. But she
9 would not have the expertise to provide
10 input on how it should run.

11 Q. Is Brian Strehlke involved
12 in this at all?

13 A. No. Just Stephanie.

14 (Document marked for
15 identification as Exhibit
16 Janssen-Dempsey-34.)

17 BY MR. JANUSH:

18 Q. I'm marking Dempsey Exhibit
19 34. This was a previously clawed back
20 document at the last deposition.

21 This is a document that
22 should look familiar to you. It's an
23 e-mail from you to Debbie Sniscak who you
24 just referred to; is that right?

1 A. Yes.

2 Q. Okay. And this is dated
3 January 23, 2018.

4 Subject, "Recommendations."
5 You wrote, "Here you go."

6 And below that it looks like
7 you lifted some of the recommendations
8 from Terrance Woodworth's audit into the
9 body of this e-mail. Is that a fair
10 characterization of this e-mail?

11 A. Yes.

12 Q. What was the reason that you
13 were transmitting Terrance Woodworth's
14 audit recommendations to Debbie Sniscak?

15 A. As I mentioned before,
16 Debbie is the business relationship
17 person with IT. So if we are getting
18 ready to approach IT to make
19 modifications or IT solution, she would
20 be the one that would take the business
21 requirements, so in this case, the
22 business requirements would be taken from
23 the recommendations, and put it into a
24 functional requirements and

1 specifications that IT can actually do
2 the programming.

3 And at this time, they were
4 evaluating what could be done in SAP and
5 what had to be done outside of SAP based
6 on all these enhancements.

7 Q. Do you recall whether Debbie
8 wrote back to you after you sent this
9 e-mail?

10 A. I don't believe she did.

11 (Document marked for
12 identification as Exhibit
13 Janssen-Dempsey-35.)

14 BY MR. JANUSH:

15 Q. And this I'm going to hand
16 you what's been marked as Dempsey Exhibit
17 35. This is JAN-MS-03060701.

18 MR. JANUSH: Copies for
19 counsel.

20 BY MR. JANUSH:

21 Q. This is an e-mail from you
22 to Christopher Villani. Who is
23 Christopher Villani?

24 A. He is in commercial, the

1 marketing group for our new product.

2 Q. What new product?

3 A. Esketamine.

4 Q. Okay. And here you were
5 addressing in the middle of the page, on
6 February 14, 2018, a recap of what took
7 place during the December workshop with
8 Terrance Woodworth, your outside auditor
9 for suspicious order monitoring; is that
10 right?

11 A. Yes.

12 Q. And it states at the bottom,
13 "The commercial excellence team
14 introduced Brian and I to Sue.
15 IntegriChain is beginning to see a future
16 need in providing companies with trend
17 analysis beyond the wholesaler to
18 pharmaceutical companies and provided the
19 following scope of work. Suspicious
20 order monitoring data analytics is new to
21 us and other companies as well. I
22 recently saw my counterparts at
23 Mallinckrodt in D.C. and I asked them
24 what they are doing and was told they are

1 paying Quintiles/IMS, now IQVia, to do
2 the analysis for them."

3 Did I read that right?

4 A. Yes, you did.

5 Q. And then you asked if the
6 attachments could be reviewed and be
7 ready -- if they could be ready to
8 provide feedback at a teleconference that
9 you'll set up next week; is that correct?

10 A. Yes.

11 Q. And the attachments, Number
12 2, one is the IntegriChain substance
13 order analytics and reporting overview,
14 dated February 14, 2018. And the other
15 is an IntegriChain statement of work
16 presented to Janssen Pharmaceuticals,
17 Inc., for controlled substance order
18 compliance, also dated February 14, 2018;
19 is that right?

20 MR. BARKER: Objection.

21 THE WITNESS: Yes.

22 MR. BARKER: You misread the
23 statement of that document.

24 THE WITNESS: Statement of

1 work presented at Janssen
2 Pharmaceuticals for controlled
3 substance order analytics.

4 BY MR. JANUSH:

5 Q. Sorry. Actually, statement
6 of work presented to Janssen
7 Pharmaceuticals, Inc., for controlled
8 substance order analytics, right?

9 A. Yes.

10 MR. BARKER: Object to form.

11 BY MR. JANUSH:

12 Q. And the statement of work is
13 Bates Number JAN-MS-03060712.

14 And the IntegriChain slide
15 deck is JAN-MS-03060704.

16 Had you met with
17 IntegriChain before February 14, 2018,
18 prior to being provided with this
19 statement of work?

20 A. I can't recall the first
21 time that I met them.

22 Q. Okay. What's your
23 understanding of what IntegriChain is --
24 let's take a step back.

1 Janssen wound up retaining
2 IntegriChain, correct?

3 A. JOM retained them last -- we
4 got the -- this SOW approved last
5 December. Janssen has been using
6 IntegriChain. The trade marketing folks
7 have been using them.

8 Q. Right. Janssen, for
9 purposes of sales and marketing, has been
10 using IntegriChain data dating back to at
11 least 2011; is that right?

12 A. I don't know the actual
13 date. But I do know that they've been
14 using this data.

15 Q. And we -- we addressed that
16 at the last deposition with a document
17 showing ValueTrak and IntegriChain data
18 in 2011 and 2012; is that right?

19 A. You did show me that trade
20 analytics slide deck.

21 Q. And when was the first time
22 that compliance started working with
23 IntegriChain?

24 A. It was when commercial

1 excellence introduced Brian Strehlke and
2 I to IntegriChain. And I don't remember
3 when. I guess it was in February.

4 Q. Of 2018?

5 A. Yeah.

6 Q. What is your understanding
7 of what IntegriChain brings to the table
8 in terms of assisting with Janssen's
9 to-be-updated or revised suspicious order
10 monitoring program?

11 MR. BARKER: Object to form.

12 THE WITNESS: What
13 IntegriChain can assist us with is
14 identifying at the pharmacy level,
15 if there's any trends with our
16 products.

17 Right now, our 867 data is
18 blinded, and IntegriChain can get
19 the unblinded data and do the
20 analysis off our data to let us
21 know at the pharmacy level, how
22 does our product compare to, I
23 guess, national averages is what
24 they explained to us. And they

1 could do regional analysis and let
2 us know if there is any trends
3 with our product that we need to
4 investigate.

5 BY MR. JANUSH:

6 Q. For example, on Page 2 of
7 the slide deck, "Identify pharmacies with
8 high volume purchasing trends leveraging
9 product and market deciles." Is that
10 right?

11 A. That is what -- yes.

12 Q. Okay. And that they can
13 also assist, based on, going to the last
14 bullet, "Based on historical purchasing
15 trends, set volume thresholds at the
16 pharmacy and distributor level. Total
17 volume can be rolled up to distributor as
18 an input into the order monitoring
19 system."

20 Do you see that?

21 A. Yes.

22 Q. Are you doing that now going
23 forward? Are you implementing this?

24 A. This is the Track 2 of our

1 project where we will be looking
2 downstream to determine whether, based on
3 what the wholesalers ship out, if we need
4 to adjust the thresholds. So, yes, our
5 new enhancements will be doing this.

6 Q. And to be clear, this is the
7 kind of third-party data vendor that
8 assists in unblinding sales that you make
9 to your distributor, such that they are
10 able to report back to you when a
11 Cardinal, as an example, may sell to a
12 CVS, they may be able to report back to
13 you which CVS store your products are
14 ending up at; is that right?

15 MR. BARKER: Object to form.

16 THE WITNESS: IntegriChain
17 can give us visibility to the CVS
18 level.

19 BY MR. JANUSH:

20 Q. Okay. This is the know your
21 customers' customer data, so to speak,
22 right?

23 MR. BARKER: Object to form.

24 BY MR. JANUSH:

1 Q. Remember we talked about
2 that concept of know your customers'
3 customer, in the context of the
4 Mallinckrodt DEA investigation?

5 MR. BARKER: Object to form.

6 THE WITNESS: We were told
7 to -- yes. Well, you need to know
8 where your products are going
9 downstream.

10 BY MR. JANUSH:

11 Q. Right. And that refers to
12 knowing your customers' customer, right?

13 A. Yes.

14 Q. And knowing your customers'
15 customer was not a new concept for you,
16 was it? You learned about this concept
17 when you benchmarked with Jack Crowley at
18 Purdue on March 21, 2012, didn't you?

19 MR. BARKER: Object to form.

20 THE WITNESS: We understood
21 that Purdue was doing that.

22 BY MR. JANUSH:

23 Q. And by doing that, what do
24 you mean?

1 A. That they were doing the
2 downstream pharmacy analysis because of
3 the oxycodone situation.

4 Q. So Purdue was knowing their
5 customers' customer; is that right --
6 what you're testifying to?

7 MR. BARKER: Object to form.

8 THE WITNESS: That is what
9 they communicated to us.

10 (Document marked for
11 identification as Exhibit
12 Janssen-Dempsey-36.)

13 BY MR. JANUSH:

14 Q. I'm going to hand you what's
15 been marked as 36. It actually is a
16 document that references the know your
17 customers' customer. Its Bates number is
18 JAN-MS-02984629, and this is when in July
19 of 2013, Jack Crowley, formerly of
20 Purdue, then on his own as Crowley
21 Associates, was pitching to Janssen an
22 abuse and diversion detection program,
23 isn't it?

24 MS. POWER: Object to form.

1 THE COURT REPORTER: Can you
2 identify who you are?

3 MS. POWER: This is Caroline
4 Power for the Purdue defendants.

5 MR. JANUSH: Representing
6 which defendant?

7 MS. POWER: The Purdue
8 defendants.

9 MR. JANUSH: Thank you.

10 BY MR. JANUSH:

11 Q. Let's go to the first line
12 of the middle of the e-mail. "Hello,
13 Ron. Here are a preliminary rough notes
14 on the subject of our recent
15 conversation. DEA impact on pharmacy
16 stocking C-II medications - developing a
17 system for your abuse and diversion
18 detection program - prescribers of
19 concern."

20 Did I read that right?

21 MR. BARKER: Object to form.

22 THE WITNESS: Yes.

23 BY MR. JANUSH:

24 Q. And it says, "We discussed

1 training for the sales force how to
2 recognize what is suspicious or a cause
3 for concern, that this is a delicate
4 balance and generally what steps need to
5 be taken to bring information into the
6 home office, so to speak, how to handle
7 that information, and how to move
8 forward."

9 Did I read that correctly?

10 MR. BARKER: Object to form.

11 THE WITNESS: Yes.

12 BY MR. JANUSH:

13 Q. And at the bottom, it's
14 addressing five different suggestions,
15 after which Jack writes, "'Know your
16 customers' customers,' Janssen's
17 suspicious or noteworthy order monitoring
18 system and collaboration/mutual support
19 with authorized distributors."

20 Did I read that correctly?

21 A. Yes.

22 Q. From July 26, 2013, when
23 Jack Crowley pitched this abuse and
24 diversion detection program that follows

1 at JAN-MS-02984631 with his presentation
2 to the present date, you didn't implement
3 a know your customers' customer program
4 to address prescribers of concern at the
5 sales force level, did you?

6 A. It wasn't an expectation.
7 We weren't told by DEA to do this. But I
8 am not aware if Ron implemented that. I
9 did not. I can't speak on behalf of Ron
10 what he did with this. But I do know
11 that I did not.

12 Q. And just to wrap up this
13 document, the attachment from Jack
14 Crowley, Bates Number JAN-MS-02984631,
15 concerned his pitch on how to address
16 prescribers of concern with a stated
17 goal, in the middle of the first page --
18 I'm going to direct your attention to the
19 first page of his title page. "Goal -
20 make sure that the company is marketing
21 to the proper prescribers."

22 Do you see that?

23 A. Yes, I do.

24 Q. "Secondary goal, to provide

1 guidance and require the sales
2 representatives to recognize, detect, and
3 report suspicious" -- "suspected abuse
4 and suspected diversion by healthcare
5 practitioners of Janssen products."

6 Do you see that?

7 MR. BARKER: Object to form.

8 THE WITNESS: Yes, I do.

9 BY MR. JANUSH:

10 Q. Do you remember internally
11 pitching this within Janssen as something
12 that you had an interest in having Jack
13 present on?

14 MR. BARKER: Object to form.

15 THE WITNESS: I recall that
16 Ron asked me if I knew anybody
17 that could talk to him about
18 training of the sales force. And
19 I introduced him to Jack Crowley.

20 BY MR. JANUSH:

21 Q. You were friends with Jack
22 though, right?

23 A. I have known Jack for many
24 years, yes.

1 Q. So if Jack got retained
2 after you introduced him, you would have
3 known that, wouldn't you?

4 A. Yes, I would have.

5 Q. And to this day, you
6 don't -- you have no knowledge that he
7 was retained, right?

8 A. He was not retained.

9 (Document marked for
10 identification as Exhibit
11 Janssen-Dempsey-37.)

12 BY MR. JANUSH:

13 Q. I'm going to move on to
14 Exhibit 37, JAN-MS-03124101.

15 MR. JANUSH: Whoops. I
16 marked the wrong one.

17 MR. BARKER: Feel free to
18 mark the one with all your notes
19 on it if you want. That's all
20 right.

21 BY MR. JANUSH:

22 Q. I'm going to just address
23 this. This is the July 24, 2013, Version
24 2, work instruction, document entitled

1 "JOM Customer Service Suspicious Or
2 Excessive Orders." Document Number DS/WI
3 3824, Version 2.0.

4 Do you see that?

5 A. Yes.

6 Q. This is the Version 2 of the
7 suspicious order monitoring program work
8 instruction that you played a role in
9 putting together after you came on board
10 as director of controlled substance
11 compliance in 2012; is that right?

12 MR. BARKER: Object to form.

13 THE WITNESS: Yes.

14 BY MR. JANUSH:

15 Q. And just for the record,
16 this -- the purpose of this is stated at
17 1.1, "To define a process that complies
18 with DEA or state requirements to provide
19 information on any prescription order,
20 controlled or noncontrolled substances,
21 that could be considered potentially
22 suspicious or excessive," right?

23 A. Yes.

24 Q. And the algorithm that

1 existed in Version 1.0 that we addressed
2 at the last deposition is the same here
3 isn't it, at 3.2. It's 300 percent of
4 the calculated 12-month per weekly order
5 average; is that right?

6 MR. BARKER: Object to form.

7 THE WITNESS: Yes. 12-month
8 per weekly order average.

9 (Document marked for
10 identification as Exhibit
11 Janssen-Dempsey-38.)

12 BY MR. JANUSH:

13 Q. I'm going to mark for you
14 Exhibit 38.

15 And this is a different
16 document. It's JOM customer support
17 services Schedule II through V order
18 processing and investigating suspicious
19 or excessive orders. This is DS SOP
20 1235, Version 7.0, found at
21 JAN-MS-03115424. And the effective date
22 of this is December 19, 2016.

23 And here too, the purpose of
24 this document is to provide instructions

1 for processing Schedule II through V
2 controlled substance orders and for
3 investigating suspicious or excessive
4 orders for controlled substances; is that
5 right?

6 A. Yes.

7 Q. And again, the algorithm is
8 stated differently. But it's stated in
9 the definition section at 3.1.

10 "Suspicious orders or excessive
11 controlled substances orders: Any
12 customers for Schedule II through V
13 orders exceeding three times the normal
14 12-month rolling demand."

15 Did I read that right?

16 A. Yes.

17 Q. And that's not 12 times the
18 normal 12-month weekly rolling demand
19 stated here. It's just 12 times the
20 normal 12-month -- three times the normal
21 12-month rolling demand; is that right?

22 MR. BARKER: Object to form.

23 THE WITNESS: That is what
24 it reads.

1 BY MR. JANUSH:

2 Q. Did you have a role in
3 drafting this document?

4 A. I reviewed it. But
5 customer -- this is a customer service
6 SOP. They wrote it.

7 Q. Did you have the ability to
8 edit the document if you thought it was
9 in error?

10 A. Yes.

11 Q. Did you ever edit that
12 document?

13 A. I don't recall.

14 (Document marked for
15 identification as Exhibit
16 Janssen-Dempsey-39.)

17 BY MR. JANUSH:

18 Q. I'm marking 39. And I'm
19 handing copies to counsel.

20 JAN-MS-03115570. This appears to be an
21 e-mail from you to Belinda Corum dated
22 November 15, 2017, concerning
23 suspicious -- titled -- the subject is
24 2017 -- November 15, 2017, "Suspicious

1 order monitoring minutes."

2 And it attaches DS/WI 3824,
3 the atypical order justification release
4 form work instruction, which can be found
5 at JAN-MS-03115575.

6 Do you see that work
7 instruction?

8 A. Getting to it. Yes.

9 Q. And have you seen this
10 document before?

11 A. I have seen this document
12 before.

13 Q. Did you ever edit this
14 document?

15 A. Yes.

16 Q. You did. Okay.

17 And here we have definition,
18 DEA unusual order quantity report at 3.1.
19 "A report that captures potentially
20 unusual quantities of controlled
21 substance orders, Schedule II through V,
22 that is equal to or greater than three
23 times (300 percent) the calculated
24 12-month order average."

1 Do you see that?

2 A. I do see that.

3 Q. That's not addressing a
4 weekly order average. That's looking at
5 the calculated 12-month order average; is
6 that right?

7 A. The way it's written, yes.

8 Q. I'm going to mark as Dempsey
9 Exhibit 40 --

10 (Document marked for
11 identification as Exhibit
12 Janssen-Dempsey-40.)

13 BY MR. JANUSH:

14 Q. -- a standard operating
15 procedure. And this is Bates-stamped
16 JAN-MS-03121360.

17 And here too, at definition
18 3.0 of Document Number DS -- standard
19 operating procedure 1235, Version 8.0
20 dated May 4, 2018, Janssen -- JOM is
21 defining a DEA questionable order report
22 as, "Identifying orders for all customers
23 ordering Schedule II to V orders that
24 exceed three times the normal 12-month

1 rolling demand." Is that right?

2 A. Yes.

3 Q. Okay. And to be clear,
4 numerous other provisions exist within
5 this document. Do you recognize this
6 document?

7 MR. BARKER: Object to form.

8 THE WITNESS: I do recognize
9 this document.

10 BY MR. JANUSH:

11 Q. Did you have a role in
12 creating the document?

13 A. It's a customer service
14 document. And at this date, I was not in
15 the approval route.

16 Q. Did you ever have the
17 opportunity to edit this document?

18 A. As you showed me in 2017, I
19 did.

20 Q. I'm going to switch gears
21 for a moment. We're going to go back to
22 the Noramco topic that we talked about
23 during Day 1 of your deposition. I've
24 marked this as Exhibit 41.

1 (Document marked for
2 identification as Exhibit
3 Janssen-Dempsey-41.)

4 BY MR. JANUSH:

5 Q. This is Bates-marked
6 JAN-00060001431, and it's a regulatory
7 agency contact report, much like what I
8 addressed with you on the first day of
9 your deposition. And here in the summary
10 it's saying, "Noramco submitted comments
11 to the 2013 proposed aggregate production
12 quota, Federal Register posting."

13 And second page in, it looks
14 to be an August 31, 2012, Noramco
15 comment, letter to the DEA, office of
16 diversion control.

17 Do I have that right?

18 A. Yes.

19 Q. Okay. And in it, you're
20 referencing Noramco's quota applications
21 by reference number for codeine,
22 morphine, morphine for conversion,
23 oxycodone for sale, oxymorphone for
24 conversion, oxymorphone for sale,

1 oxymorphone for sale again, oripavine,
2 hydromorphone, hydrocodone for sale, and
3 methylphenidate; is that right?

4 MR. BARKER: Object to form.

5 THE WITNESS: Yes.

6 BY MR. JANUSH:

7 Q. And there's also a letter
8 dated August 31, 2012, where you're
9 addressing your quota application, your
10 quota reference numbers. But also
11 addressing the 2013 April submission of
12 base kilograms and the revised 2013 quota
13 kilograms base, and the change between
14 the two; is that right?

15 A. Yes.

16 Q. Okay. And jumping forward
17 to the page ending in 1440. You are
18 addressing the rationale for demand
19 increase for morphine. And in it, in
20 this letter of August 31, 2012, you
21 state, "As communicated in the July 27,
22 2012, quota request, morphine sales are
23 holding steady. Noramco 2012 sales to
24 Purdue and Roxane Boehringer Ingelheim

1 were well above forecast due to
2 continuing marketing adjustments from the
3 Novartis manufacturing issues."

4 Did I read that right?

5 A. Yes.

6 Q. And then down below, you
7 show sales to Purdue -- or forecasts,
8 excuse me, of base kilograms of morphine
9 to Purdue at 6,825 base kilograms; is
10 that correct?

11 A. Yes.

12 Q. And for Actavis Elizabeth
13 LLC, 1,875 base kilograms, right?

14 A. Yes.

15 Q. And for Actavis Elizabeth
16 LLC there's an additional 26 kilograms
17 listed above that; is that right?

18 A. Yes.

19 Q. And now I'm going to have
20 you move forward to the document, Page
21 Number 1443. And here you're addressing
22 the rationale for demand increase
23 oxycodone; is that correct?

24 A. Yes.

1 Q. And you are addressing
2 that -- at the bottom bullet, "Noramco
3 has numerous supply agreements for
4 oxycodone hydrochloride. The most
5 impactful and important agreements based
6 on the market position of the companies
7 are with Actavis, greater than or equal
8 to 90 percent; Watson, greater than or
9 equal to 90 percent; Endo/Qualitest,
10 greater than or equal to 80 percent; and
11 Amneal, greater than or equal to
12 90 percent."

13 Did I read that right?

14 MR. BARKER: Object to form.

15 THE WITNESS: Yes.

16 BY MR. JANUSH:

17 Q. So is this confirming that
18 Noramco has agreements to supply these
19 companies with greater than 90, 90, 80,
20 and 90 percent respectively of their
21 total projected oxycodone --

22 MR. BARKER: Object to form.

23 BY MR. JANUSH:

24 Q. -- API?

1 MR. BARKER: Object to form.

2 THE WITNESS: The way that
3 it's described, it is -- it's
4 stating that of their market
5 share, Noramco has supply
6 agreements in place to provide
7 90 percent of their market.

8 BY MR. JANUSH:

9 Q. So 90 percent of Actavis'
10 market, 90 percent of Watson's market,
11 80 percent of Endo and Qualitest's market
12 and 90 percent of Amneal's market; is
13 that right?

14 A. That is what it states.

15 MR. BARKER: Object to form.

16 BY MR. JANUSH:

17 Q. Moving to the next page,
18 oxycodone contract volumes. It says in
19 the bottom of this box, "Percentage of
20 total oxycodone hydrochloride domestic
21 sales, 60,218 kilograms as base." And it
22 shows 68.1 percent of the 2013 forecast
23 kilograms as base, and 73.7 percent of
24 the 2013 contract kilograms as base; is

1 that right?

2 MR. BARKER: Object to form.

3 THE WITNESS: That is what
4 it states.

5 BY MR. JANUSH:

6 Q. And does this mean that you
7 had -- that Noramco had 68.1 percent of
8 the forecast market for oxycodone
9 hydrochloride --

10 MR. BARKER: Object to --

11 BY MR. JANUSH:

12 Q. -- at this time?

13 MR. BARKER: Object to form.

14 THE WITNESS: It states that
15 in the next year, based on what
16 the customers have told us and our
17 contracts, that this is the
18 percent.

19 BY MR. JANUSH:

20 Q. Okay. And I'm going to have
21 you move forward to the document, Page
22 1449.

23 This is addressing the
24 rationale for demand increase of

1 oxymorphone; is that right?

2 A. Yes, it is.

3 Q. And the first bullet says,
4 "The total demand for oxymorphone for
5 conversion is driven by supplying
6 intermediates to Rhodes Technologies."
7 Rhodes is Purdue, correct?

8 MR. BARKER: Object to form.

9 THE WITNESS: I believe it's
10 a subsidiary. I'm not -- I don't
11 remember --

12 BY MR. JANUSH:

13 Q. It's a wholly subsidiary of
14 Purdue that makes their raw API according
15 to your deposition testimony from
16 January 22nd, right?

17 MR. BARKER: Object to form.

18 BY MR. JANUSH:

19 Q. You may answer.

20 A. That is what I understood.

21 Q. And here you're addressing
22 that in regards to oxymorphone
23 hydrochloride demand, Noramco is
24 experiencing API supplier shifts, and

1 unexpectedly Noramco received increase
2 from virtually every generic who
3 originally formulated with Mallinckrodt
4 material.

5 Do you see that, that
6 sentence? I skipped a sentence. But do
7 you see that?

8 MR. BARKER: Object to form.

9 THE WITNESS: Yes.

10 BY MR. JANUSH:

11 Q. Okay. Do you know why
12 Noramco received -- why -- why other
13 folks, other generics switched and moved
14 away from Mallinckrodt?

15 MR. BARKER: Object to form.

16 THE WITNESS: No.

17 BY MR. JANUSH:

18 Q. Okay. And there's also a
19 rationale for demand increase for
20 hydrocodone; is that right? And that's
21 on Page 1457.

22 MR. BARKER: Object to form.

23 THE WITNESS: Yes, it is.

24

1 BY MR. JANUSH:

2 Q. And going to the bottom of
3 the box, 2013 forecast kilograms as base.
4 Percentage of total Noramco forecast, you
5 list 89 percent. What does that
6 89 percent mean?

7 MR. BARKER: Object to form.

8 THE WITNESS: I'm sorry.

9 Can you show me where the
10 89 percent is.

11 BY MR. JANUSH:

12 Q. Yeah, I'll circle it in
13 blue.

14 A. Oh, down there. Okay.

15 MR. BARKER: Object to form.

16 THE WITNESS: So what it is
17 saying is based on what the
18 customers have told us for next
19 year, the total quantity
20 against -- I'm not quite sure.
21 Well, okay, yes, I understand.

22 Of the total demand we're
23 receiving for hydrocodone, these
24 top three customers are 89 percent

1 of it.

2 BY MR. JANUSH:

3 Q. And below that grid, it
4 says, "Taken together, Noramco's top
5 three customers represent approximately
6 74 percent of the hydrocodone market.
7 All discussions and contracts to date
8 indicate our customers intend to keep
9 buying at or near the percentages shown
10 above."

11 Did I read that right?

12 A. Yes.

13 Q. So Noramco was producing raw
14 API for its top three customers that
15 represented approximately 74 percent of
16 the hydrocodone market; is that correct?

17 MR. BARKER: Object to form.

18 THE WITNESS: Noramco
19 produced hydrocodone, what the
20 manufacturing quota granted by
21 DEA, that did represent 74 percent
22 of the hydrocodone market.

23 BY MR. JANUSH:

24 Q. Okay. And incidentally at

1 the last page --

2 MR. BARKER: You've exceeded
3 your time. Are you close?

4 MR. JANUSH: Ten seconds.

5 MR. BARKER: Okay, go.

6 MR. JANUSH: Thanks.

7 BY MR. JANUSH:

8 Q. Going to Page 1464, just to
9 wrap up this document, this letter was
10 submitted by you, and that's your
11 signature with all -- that's your
12 signature below all of the data that I
13 was just addressing; is that right?

14 MR. BARKER: Object to form.

15 THE WITNESS: That is my
16 signature. But this letter was a
17 compilation of many people doing
18 it.

19 BY MR. JANUSH:

20 Q. But ultimately it went out
21 over your name, right?

22 A. My name was on it.

23 Q. And your name was on it as
24 director of process engineering and DEA

1 compliance; is that right?

2 A. Yes.

3 Q. At the same time that you
4 were serving -- is this at the same time
5 that you were serving as director of
6 controlled substance compliance for JOM?

7 MR. BARKER: Object to form.

8 THE WITNESS: Yes, I did.

9 BY MR. JANUSH:

10 Q. So you were serving in two
11 distinctly different roles, one for
12 Noramco as listed here, and one for JOM
13 as director of controlled substance
14 compliance, correct?

15 A. Yes.

16 MR. JANUSH: I have no
17 further questions at this time.

18 MR. BARKER: I appreciate
19 that. Do you want to break for
20 lunch here?

21 MR. JANUSH: Sure.

22 THE VIDEOGRAPHER: All
23 right. The time is 1:05 p.m. Off
24 the record.

1 (Lunch break.)

2 THE VIDEOGRAPHER: We are
3 back on the record. The time is
4 2:16 p.m.

5 - - -

6 EXAMINATION

7 - - -

8 BY MR. BARKER:

9 Q. Good afternoon, Ms. Dempsey.

10 A. Hi.

11 Q. We've already covered a
12 number of these things, but just so we
13 can get them out in a solid line of
14 questioning. I'm going to cover a few
15 things that Mr. Janush covered but I'm
16 going to cover them very quickly.

17 You graduated from Villanova
18 in 1986 with a bachelor of science in
19 chemical engineering, correct?

20 A. Yes.

21 Q. Noramco was your first job
22 after graduating?

23 A. Yes.

24 Q. You held several positions

1 at Noramco, correct?

2 A. Yes.

3 Q. When did you start handling
4 suspicious order monitoring for Noramco?

5 A. When I took over DEA
6 compliance at the end of 2007 I became
7 aware of the requirement for suspicious
8 order monitoring.

9 Q. Okay. And what training did
10 you receive for handling suspicious order
11 monitoring?

12 A. I attended DEA conferences.
13 Plus we had internal training about the
14 Controlled Substance Act.

15 Q. And did you have training on
16 how to handle inspections?

17 A. Yes.

18 Q. And how about handling
19 customer complaints?

20 A. Yes.

21 Q. And how about reporting
22 suspicious orders or other activities?

23 A. Yes.

24 Q. When did you first become

1 involved in DEA compliance for a Johnson
2 & Johnson company outside of Noramco?

3 A. In 2011.

4 Q. And how is it that you
5 became involved in DEA compliance for a
6 Johnson & Johnson company outside of
7 Noramco?

8 A. I was asked to consult and
9 advise the other locations within the
10 United States that handled controlled
11 substances.

12 Q. Thanks. And when did the
13 Janssen suspicious order monitoring
14 program become part of your
15 responsibilities?

16 A. In first quarter of 2012.

17 Q. Okay. And what sort of
18 training did you receive when you were
19 asked to take on the Janssen suspicious
20 order monitoring responsibilities?

21 A. I was still attending the
22 DEA courses. And then in 2013, DEA held
23 their first distributor conference which
24 I attended. And then I was introduced to

1 the HDMA conferences where they have a
2 special track on compliance items like
3 suspicious order monitoring where DEA
4 speaks to distributors.

5 Q. What was your title when you
6 took over responsibilities for Janssen's
7 suspicious order monitoring?

8 A. Director of controlled
9 substance compliance.

10 Q. Okay. And is that still
11 your title today?

12 A. Yes.

13 Q. I'd like to discuss the
14 evolution of the Janssen suspicious order
15 monitoring program in more detail.

16 When you first became
17 involved in Janssen's suspicious order
18 monitoring program, what was your
19 understanding as to when that program
20 came into being?

21 A. I learned that the algorithm
22 that was currently being used was
23 implemented in 2006.

24 Q. Okay. And do you have an

1 understanding as to whether there was a
2 program in place to monitor potentially
3 suspicious orders before that one?

4 A. I was aware that in the
5 previous year there was a manual process.

6 MR. BARKER: Okay. Let's
7 mark as Exhibits 42-A, B, and C.

8 (Document marked for
9 identification as Exhibit
10 Janssen-Dempsey-42-A.

11 (Document marked for
12 identification as Exhibit
13 Janssen-Dempsey-42-B.

14 (Document marked for
15 identification as Exhibit
16 Janssen-Dempsey-42-C.)

17 MR. BARKER: Documents that
18 begin with the Bates Numbers
19 JAN-MS-03741177 running through
20 41200. 42-B is JAN-MS-0374110
21 running through 76, and 42-C is
22 374 -- excuse me, JAN-MS-03741201
23 through 05.

24 BY MR. BARKER:

1 Q. Ms. Dempsey, do you have
2 Exhibits 42-A, B, and C in front of you?

3 A. Yes, I do.

4 Q. Okay. Do you recognize
5 these documents?

6 A. Yes.

7 Q. What are they?

8 A. They are JOM SOPs from -- I
9 had to check the back, from 2015 that
10 covers how customer service process
11 orders, how they handle excessive and
12 suspicious orders, and then the
13 investigations.

14 Q. Okay. And were these the
15 SOPs or -- we've actually used the term
16 SOP quite a bit today. I don't think
17 anybody asked you. What is an SOP?

18 A. Standard operating
19 procedure.

20 Q. And what are standard
21 operating procedures used for?

22 A. They are used to document
23 how a process is supposed to be executed.

24 Q. And were the three SOPs that

1 have been marked as 42-A, B, and C in
2 place before the automated suspicious
3 order monitoring system was created?

4 MR. JANUSH: Objection.

5 THE WITNESS: That is what I
6 was told, yes.

7 BY MR. BARKER:

8 Q. Okay. And do the three
9 documents that we've marked as 42-A, B,
10 and C come from Janssen's files?

11 A. They come from JOM, Janssen
12 Ortho-McNeil's documentation system.

13 Q. As the director of
14 controlled -- controlled substance
15 compliance, do you understand that they
16 were created in the ordinary course of
17 business and maintained in the ordinary
18 course of business?

19 A. Yes.

20 Q. I want to direct your
21 attention to 42-B. And let's turn to
22 Page 3 of 42-B. And in particular, I'll
23 direct your attention to Paragraph 8.1.4.

24 Can you please read what it

1 says?

2 A. "Highlight any order with a
3 percent variance value greater than three
4 times the customers average order over a
5 52-week period."

6 Q. Okay. And what was that
7 process used for in these 2005 SOPs?

8 A. So this SOP documented how
9 they manually downloaded historical data
10 and compared the current order against
11 this threshold.

12 Q. Okay. And this calculation
13 was done by hand in the 2005 process?

14 A. Yes.

15 Q. Now, there are three SOPs
16 here. What's the difference between
17 them?

18 A. Well, this first one, B,
19 42-B, describes how to get the data out
20 of SAP and review it.

21 42-A goes into how 222s are
22 processed and confirmed to be accurate
23 and the order gets placed into SAP. And
24 just basically how an order gets reviewed

1 and then released to ship.

2 Q. Okay. Let me ask you to
3 pause there.

4 Does the customer service
5 SOP have anything to do with the flagging
6 of an order for review?

7 A. I am trying to find out if
8 it does. Apologies. That's how they do
9 the order report. Process of printed
10 out. So this is basically just how they
11 process it into the system.

12 Q. Okay. And does that have
13 anything to do with how an order gets
14 flagged for potential review as a --

15 A. No. Because 42-B did.

16 Q. Okay. Let me finish my
17 question before you go to the answer.

18 Does that have anything to
19 do with how an order gets flagged for
20 further review?

21 A. 42-A doesn't.

22 Q. And what's the third SOP?

23 A. The third SOP is the
24 instructions for investigating suspicious

1 or excessive orders.

2 Q. Going back to 42-B and, in
3 particular, the paragraph that we were
4 looking at before, 8.1.4. Do you have an
5 understanding as to where the threshold
6 of looking for orders with a percent
7 variance value greater than three times
8 the customer's average order over a
9 52-week period came from?

10 A. It was DEA guidance that was
11 provided on the website in the chemical
12 handler handbook.

13 (Document marked for
14 identification as Exhibit
15 Janssen-Dempsey-43.)

16 BY MR. BARKER:

17 Q. I'm going to mark as
18 Exhibit 43 a document entitled chemical
19 handlers manual, Appendix E-3,
20 "Suspicious order reporting system for
21 use in automated tracking systems."

22 This is a two-page document.

23 Do you have Exhibit 43 in
24 front of you?

1 A. Yes.

2 Q. Do you recognize it?

3 A. Yes.

4 Q. What is it?

5 A. It is a guidance document
6 that DEA put on their website to describe
7 how to set up thresholds in suspicious
8 order reporting systems.

9 Q. Was this a document that DEA
10 just posted or was it a document that was
11 providing guidance to the manufacturing
12 community?

13 A. It was part of the chemical
14 handler manual, which provides guidance
15 to industry.

16 MR. JANUSH: I'm going to
17 object and note for the record
18 that this is dated -- that it was
19 pulled from the web and printed on
20 February 28, 2019. And I'm going
21 to ask for some clarification as
22 to whether you have any evidence
23 or proof that this related to the
24 time period of 2005 that you were

1 addressing with the prior SOPs.

2 MR. BARKER: Well, the date
3 of the document is in the upper
4 right-hand side. But the witness
5 also knows the document from the
6 time period. The fact that it's
7 just pulled recently off the DEA's
8 website doesn't matter here or
9 there.

10 MR. JANUSH: Where is the
11 date of the document in the upper
12 right-hand side?

13 MR. BARKER: It's in the
14 search box up there. It's showing
15 the capture.

16 THE WITNESS: April 17,
17 2001.

18 MR. BARKER: April 17, 2001.

19 MR. JANUSH: Through
20 October?

21 MR. BARKER: I will help you
22 out. Look on the screen.

23 THE WITNESS: You can move
24 it down.

1 MR. BARKER: Sorry.

2 BY MR. BARKER:

3 Q. So is this the source that
4 you were thinking of when you said that
5 the three times metric came from the DEA?

6 A. Yes.

7 Q. And where is the metric that
8 were you describing?

9 A. Each step tells you, you
10 take the last 12 months. You calculate
11 the total purchase a month, multiply --
12 the average, you multiply by a factor
13 below to give the maximum amount that a
14 customer can other per month before
15 showing up on the suspicious order
16 report. And factor equals three for
17 Schedule IIs and Schedule IIIs controlled
18 substances containing List 1 chemicals
19 and eight for Schedule III, IV and V
20 controlled substances and noncontrolled
21 over-the-counter products.

22 Q. Has the DEA ever provided
23 any other guidance as to what thresholds
24 should be used to determine if a purchase

1 quantity is excessive?

2 A. No.

3 Q. You can put that aside.

4 You mentioned during your
5 testimony that the current suspicious
6 order monitoring program at Janssen
7 started in 2006, correct?

8 A. The algorithm, yes.

9 Q. The algorithm. And what's
10 the difference between the algorithm and
11 the suspicious order monitoring process
12 itself?

13 A. The algorithm is just one
14 part of it. You also have the
15 investigation and the investigation of
16 the orders.

17 Q. Okay. And what changed from
18 what Janssen was doing in 2005 as
19 outlined in the SOPs that we just looked
20 at, versus what was being done in 2006?

21 A. In 2005, the algorithm was a
22 manual calculation. In 2006, we moved
23 the algorithm to the SAP system that was
24 receiving the customers orders.

1 Q. And what is your
2 understanding as to what the
3 computer-based system is now doing?

4 A. It is taking all the history
5 of the past 12 months of each customer
6 for every SKU that they order,
7 calculating this threshold on a rolling
8 basis, and comparing every realtime order
9 against this threshold.

10 Q. Okay. And if an order is
11 flagged by this algorithm, what then
12 happens?

13 A. There's an investigation
14 process whereby we engage the customer to
15 understand why there's an increase in
16 demand, and they provide us a
17 justification. And then the data is
18 reviewed by the DEA compliance manager or
19 quality assurance, and the order is
20 released if the justification makes
21 sense, and I would document that
22 discussion.

23 Q. Okay. Previously in
24 questioning you, Mr. Janush described the

1 algorithm, the three times 12-month
2 rolling weekly average, as "fourth grade
3 simple math."

4 Do you recall that?

5 A. Yes.

6 Q. Do you agree that the
7 execution of the algorithm in the
8 computer program is fourth grade simple
9 math?

10 A. No.

11 Q. Why not?

12 A. Because SAP is a validated
13 system that FDA obviously inspects. And
14 any code that is programmed requires a
15 lot of effort around validating. So
16 anytime -- you know, to go back to find
17 the code that records the order history
18 and pull it out and extract it, you have
19 to do a functional requirement that IT
20 can make the specification against. Then
21 we also have a test script where we're
22 saying for this -- say pull the history
23 from 12 months ago. We have to confirm
24 that SAP is going back to the right

1 dataset and pulling it out. And then if
2 it is, you have to confirm it. And then
3 it all gets signed off as validation.

4 So every single component,
5 everything that you take for granted that
6 you may download in Excel, every action,
7 has to be programmed in the computer.

8 Q. Okay.

9 (Document marked for
10 identification as Exhibit
11 Janssen-Dempsey-44.)

12 MR. BARKER: Let's mark as
13 Exhibit 44 -- I guess I should
14 apologize to the court reporter.
15 This is Exhibit 44.

16 It is -- I'm not exactly
17 sure -- it's not going to work
18 over there.

19 BY MR. BARKER:

20 Q. So Exhibit 44 begins with
21 Bates Number JAN-MS-05444824 and runs
22 through JAN-MS-05446674.

23 I'm just going to take off
24 my microphone and walk this over to you

1 rather than take the chance of passing it
2 across the table.

3 Do you have Exhibit 44 in
4 front of you?

5 MR. BARKER: We need to pass
6 one over to him too.

7 BY MR. BARKER:

8 Q. Go ahead and take a moment
9 and unbundle that. Take a look at it.
10 My first question is going to be, do you
11 recognize it?

12 A. It's the information I
13 requested be retrieved.

14 Q. And what information did you
15 request be retrieved?

16 A. The validation documentation
17 for the algorithm.

18 Q. And do the materials that we
19 have marked collectively as Exhibit 44
20 come from JOM's files?

21 A. Yes. It's the record
22 retention for IT.

23 Q. Okay. And so these are
24 records that were generated in the

1 ordinary course of business?

2 A. Yes.

3 Q. And maintained in the
4 ordinary course of business?

5 A. Yes.

6 MR. JANUSH: Let the record
7 reflect that less than 60 seconds
8 has passed for the witness to
9 answer that question for a stack
10 that's about 11 and a half inches
11 tall.

12 MR. BARKER: Well, that's
13 fine. She said she recognized.

14 THE WITNESS: This is very
15 familiar because I ran an SAP
16 project.

17 MR. JANUSH: That's fine. I
18 just want the record to reflect
19 what I said.

20 THE WITNESS: Okay. Okay.

21 BY MR. BARKER:

22 Q. Take all the time that you
23 need to confirm that this is the document
24 that you think it is.

1 A. Yes. All the technical
2 design documentation.

3 Q. Do you need any more time to
4 review the document?

5 A. I'm familiar with the
6 acronym TCPA test scripts, but yes, it's
7 all the DEA still.

8 Q. I'll ask the question that I
9 asked before. I'll ask it again. Having
10 reviewed more of Exhibit 44, do you
11 recognize this as documentation that was
12 generated in the ordinary course of
13 business and maintained in the ordinary
14 course of business relating to the
15 validation of the 2006 Janssen suspicious
16 order monitoring process algorithm?

17 A. Yes.

18 Q. Would you need to run
19 validation reports like this if all the
20 computer was doing was fourth grade
21 simple math?

22 A. No.

23 Q. You can put that aside.
24 You mentioned during your

1 prior testimony -- excuse me. You
2 previously testified that over time,
3 enhancements had been made to the Janssen
4 suspicious order monitoring program,
5 correct?

6 A. Yes.

7 Q. Were these changes made
8 because the DEA said that Janssen's
9 suspicious order monitoring program was
10 inadequate in any way?

11 A. No.

12 Q. So why were the enhancements
13 being made over time?

14 A. Well, over time through
15 attending conferences and various other
16 conferences about controlled substances,
17 whether DEA led them or not, we learned
18 of other expectations that may be
19 required and we proactively wanted to
20 make sure our system and our processes
21 were enhanced to have what we thought DEA
22 may expect us to have in our program.

23 Q. Okay. And the regulations
24 related to the Controlled Substance Act,

1 those haven't changed over time, have
2 they?

3 A. No, they haven't.

4 Q. Mr. Janush asked you a bunch
5 of questions to establish that point,
6 correct?

7 A. Yes.

8 Q. Okay. But have DEA's
9 expectations as to what information
10 registrants, such as manufacturers,
11 should be reviewing and considering
12 changed over time?

13 MR. JANUSH: Objection.

14 THE WITNESS: They have, in
15 that they expected -- they
16 communicate at conferences what
17 they expect manufacturers and
18 distributors to know about the
19 customer.

20 BY MR. BARKER:

21 Q. And has that information
22 changed over time?

23 MR. JANUSH: Objection.

24 THE WITNESS: Yes.

1 BY MR. BARKER:

2 Q. Did you or your team have
3 discussions with the DEA about how
4 Janssen's suspicious order monitoring
5 program operated?

6 A. Yes.

7 Q. Did you show them your SOPs?

8 MR. JANUSH: Objection.

9 THE WITNESS: Yes.

10 BY MR. BARKER:

11 Q. Did you discuss with them
12 what types of orders you were
13 investigating and what types of orders
14 you would deem suspicious and report to
15 them if necessary?

16 A. Yes.

17 MR. JANUSH: Objection. Is
18 there a time frame for that
19 question?

20 BY MR. BARKER:

21 Q. I'm talking about it did you
22 do it at any point in time?

23 A. Yes.

24 Q. Okay. When was the first

1 such discussion with the DEA about your
2 suspicious order monitoring program that
3 you can recall?

4 A. 2007.

5 MR. BARKER: Let's mark as
6 Exhibit 45 a document beginning
7 with Bates Numbers JAN-MS-03124082
8 continuing through 087.

9 (Document marked for
10 identification as Exhibit
11 Janssen-Dempsey-45.)

12 BY MR. BARKER:

13 Q. Do you have Exhibit 45 in
14 front of you?

15 A. Yes, I do.

16 Q. Do you recognize it?

17 A. Yes, I do.

18 Q. What is it?

19 A. It is a regulatory agency
20 contact report, a RACR, that was prepared
21 to document discussions with San
22 Francisco DEA.

23 Q. Okay. And you used the term
24 "RACR." Is that the acronym R-A-C-R?

1 A. Yes.

2 Q. Are RACRs prepared in the
3 ordinary course of business by
4 responsible employees involved in the
5 communications with the DEA?

6 A. Yes.

7 Q. And are these RACRs
8 maintained in the ordinary course of
9 business by Janssen?

10 A. Yes.

11 Q. And they are prepared at or
12 about the time of the conversations in
13 question, correct?

14 A. Yes.

15 Q. In preparing for your
16 deposition, did you attempt to locate any
17 documents relating to communications with
18 the DEA about suspicious order
19 monitoring?

20 A. Yes.

21 Q. Was this one of the
22 documents that was located?

23 A. Yes.

24 Q. Where did you get it?

1 A. Brian Strehlke provided it
2 to me.

3 Q. Okay. And you see
4 Mr. Strehlke's name here as the Johnson &
5 Johnson contact?

6 A. Yes.

7 Q. Does Mr. Strehlke currently
8 report to you?

9 A. Yes, he does.

10 Q. Okay. Now, I want to direct
11 your attention to the page beginning with
12 Bates 4086. And here we have an e-mail
13 chain between Mr. Strehlke and someone
14 named William R. Davis.

15 Do you know who Mr. Davis
16 is?

17 A. He is the diversion program
18 manager for San Francisco.

19 Q. And how do you know that?

20 A. It's on the front page.

21 Q. So you're referring to the
22 front page of this exhibit.

23 A. Mm-hmm.

24 Q. There we have Mr. Davis.

1 And where did you get his position from?

2 A. Position is right underneath
3 there.

4 Q. And his district, as you
5 said, was San Francisco. Okay.

6 Let's go back to that
7 e-mail. And down at the bottom of the
8 page there is a header from an e-mail
9 from Mr. Strehlke to Mr. Davis, right?
10 But the e-mail starts on the next page.

11 And what was the nature of
12 this contact with DEA?

13 A. We were seeing some
14 increased demand at some of the local DCs
15 for Cardinal as a result of -- there were
16 a few other DCs that had their licenses
17 suspended. So this increase in demand
18 was flagged on our system because it was
19 an increase to what they typically order.
20 And so we wanted to get guidance from DEA
21 on our interpretation to confirm that our
22 thinking is, they're a large distributor,
23 we understand why there's an increase in
24 demand, and you know, they're not

1 suspicious.

2 Q. Was there any change in the
3 pattern of Cardinal's ordering that
4 caused Mr. Strehlke to do a further
5 investigation of the orders?

6 MS. BOODY: Object to form.

7 THE WITNESS: Typically the
8 orders were sent to several
9 Cardinal DCs. And as a result of
10 recent actions they were
11 redirecting it. So there was a
12 change in the pattern.

13 BY MR. BARKER:

14 Q. Okay. New DCs were placing
15 orders, correct?

16 A. Yes.

17 Q. And did Mr. Strehlke discuss
18 with the DEA what algorithm was being
19 used to flag the suspicious orders?

20 A. He wrote an e-mail to DEA
21 how our suspicious order quantity
22 trigger, which is three times the average
23 order of the last 12 months.

24 Q. Right. You are reading that

1 from right here in the document?

2 A. Yeah.

3 Q. Okay. He's also telling the
4 DEA that you do not regard these orders
5 as being suspicious, correct?

6 A. Correct.

7 Q. And what were the reasons
8 why this order was not deemed to be
9 suspicious?

10 A. The total quantity that
11 Cardinal was ordering was consistent. It
12 was just the direction of which local DC
13 was receiving it.

14 Q. And he asked a question to
15 the DEA at the bottom, correct?

16 A. Yes.

17 Q. What was the question?

18 A. "Does DEA have any objection
19 to our filling the increased orders to
20 Cardinal DCs which have registrations
21 which are still in good standing?"

22 Q. And he's asking you that
23 because you knew that some distribution
24 centers had had their DEA registrations

1 placed on hold, correct?

2 A. Yes.

3 Q. Let's go up one e-mail.

4 When we go up one e-mail, we see

5 Mr. Davis. That's the DEA agent, right?

6 A. Yes.

7 Q. And he responds in all caps.

8 "Brian, I have forwarded

9 your questions to our associate chief

10 counsel for diversion. The San Francisco

11 division is not directly involved with

12 this investigation, so I want someone to

13 knows the restrictions to respond to you

14 directly concerning Cardinal issues."

15 Did I read that correctly?

16 A. Yes.

17 Q. Okay. So is it your

18 understanding that he kicked the request,

19 including the statement about how

20 suspicious orders were being flagged, up

21 another level within the DEA?

22 A. To headquarters, yes.

23 Q. Okay. And then above that,

24 there's a further e-mail from

1 Mr. Strehlke to Mr. Davis, right?

2 A. Mm-hmm.

3 Q. And he also copies somebody
4 else. Somebody named David Barber. Do
5 you know who David Barber is?

6 A. As you saw from the previous
7 e-mail, he is the associate chief counsel
8 for diversion.

9 Q. He's the person to whom it
10 was sent that's higher up?

11 A. Yes. Mm-hmm.

12 Q. Okay. And here --

13 MR. JANUSH: What page are
14 you at?

15 MR. BARKER: This is page --
16 ending in Bates 086.

17 MR. JANUSH: Thank you.

18 BY MR. BARKER:

19 Q. And he writes here, "We do
20 not want to risk patients not getting
21 needed medication and plan to fill these
22 orders."

23 Do you see that?

24 A. Yes.

1 Q. And then he tells the DEA
2 what the sites are, where the orders will
3 be shipped, correct?

4 A. He does not -- he relays the
5 sites that have the registration
6 suspended.

7 Q. Correct.

8 A. And then the remaining
9 Cardinal facilities are already -- they
10 have their licenses intact and they're in
11 good standing.

12 Q. So he's acknowledging which
13 ones are not going to get it. I actually
14 said the inverse.

15 A. Yes.

16 Q. Okay. And he says exactly
17 which controlled substance products were
18 going to be shipped, correct?

19 A. Yes.

20 Q. And then finally he says,
21 "Please get back to me if the agency is
22 looking for a different approach,"
23 correct?

24 A. Yes.

1 Q. Do you know if these orders
2 shipped?

3 A. Yes.

4 Q. And what was the DEA's
5 response, if any, to this inquiry?

6 A. If you go to the first page.

7 Q. Yes.

8 A. It says Mr. Davis -- said
9 called Brian back. Said, "He sent the
10 inquiry to David Barber, associate chief
11 counsel for diversion, who is heading up
12 the Cardinal investigation. He responded
13 to Mr. Davis that "DEA would not tell us
14 not to fill orders for a registrant in
15 good standing. Mr. Davis said that our
16 approach sounded good and was a
17 reasonable response to this situation."

18 Q. And in your experience, is
19 it typical that DEA provides advice and
20 guidance of this type orally on the phone
21 and not in a written letter or e-mail?

22 A. Yes.

23 Q. You can put that aside.

24 MR. BARKER: Let's mark as

1 Exhibit 46 an e-mail dated
2 October 22, 2008, from Maryann
3 Gribbin to a host of people.

4 It is Bates-numbered
5 JAN-MS-05433748 to 49.

6 (Document marked for
7 identification as Exhibit
8 Janssen-Dempsey-46.)

9 BY MR. BARKER:

10 Q. Do you have Exhibit 46 in
11 front of you?

12 A. Yes, I do.

13 Q. Okay. When you're done
14 taking a look at it, let me know whether
15 you recognize it.

16 A. Yes, I do recognize this.

17 Q. What is it?

18 A. It is a daily summary of a
19 DEA inspection.

20 Q. Okay. And are summaries of
21 FDA -- excuse me. Are summaries of DEA
22 inspections generally circulated by
23 e-mail?

24 A. Yes.

1 Q. And are such e-mails
2 prepared in the ordinary course of
3 business by somebody who was present for
4 the inspection?

5 A. Yes.

6 Q. And is it part of their job
7 to accurately summarize what happened at
8 the inspection?

9 A. Yes.

10 Q. And are such records
11 maintained by Janssen in the ordinary
12 course of business?

13 A. Yes.

14 Q. And so this -- this is
15 different than a RACR, correct?

16 A. Yes.

17 Q. Okay. Why is a RACR not
18 prepared for an inspection?

19 A. It was just different
20 purposes. The RACR is when there is --
21 when you are seeking interpretation of
22 regulations or policies. And then this
23 is just reporting out on what an
24 inspection -- what happened during --

1 it's any regulatory inspection, not just
2 DEA. This just happens to be a summary
3 from a DEA inspection, that is sent out
4 to senior leaders.

5 Q. Understood. So who is
6 Maryann Gribbin, the author of this
7 e-mail?

8 A. She was the quality leader
9 at JOM at the time.

10 Q. And was she the one with
11 responsibility to generate a report on
12 inspections?

13 A. Yes.

14 Q. When did this particular
15 inspection take place?

16 A. October 22, 2008.

17 Q. And where did it take place?

18 A. At a Franklin distribution
19 center in New Jersey.

20 Q. And is that what FDC is,
21 Franklin distribution center?

22 A. Yes.

23 Q. I want to direct your
24 attention to the second page under the

1 heading "Preparation for Day 2."

2 Are you there?

3 A. Yes.

4 Q. And it says here,

5 "Investigators are expected to complete
6 the inventory reconciliation, review
7 handling of suspicious orders and conduct
8 a security review."

9 A. Yes.

10 Q. Is it your understanding
11 that those types of inspections are
12 generally done by the DEA when they come
13 to one of your facilities?

14 A. Yes.

15 Q. And are you aware of any
16 other report relating to day two of this
17 particular inspection?

18 A. I don't know.

19 Q. Is it -- is it your -- have
20 you ever experienced a situation where
21 the DEA did not come back on the second
22 day of a scheduled two-day inspection?

23 MR. JANUSH: Objection.

24 THE WITNESS: No. They

1 usually return. It may be not --
2 be the next day if something comes
3 up, but they do return.

4 BY MR. BARKER:

5 Q. So to the best of your
6 knowledge, would you expect that the
7 suspicious order monitoring materials
8 were provided, or -- actually, strike
9 that.

10 Is it your understanding
11 that information about suspicious order
12 monitoring was provided to the inspectors
13 at the Franklin distribution center as
14 part of this inspection?

15 MR. JANUSH: Objection.

16 Calls for speculation.

17 THE WITNESS: Yes.

18 BY MR. BARKER:

19 Q. Was there ever a negative
20 review or citation as a result of this
21 inspection at the Franklin distribution
22 center?

23 A. Not that I recall.

24 Q. Did anyone from the DEA

1 communicate to Janssen after the
2 inspection at the Franklin distribution
3 center that there was a problem or an
4 issue with Janssen's suspicious order
5 monitoring program?

6 MR. JANUSH: Objection.

7 THE WITNESS: Not that I was
8 aware of.

9 BY MR. BARKER:

10 Q. What I'm going to hand you
11 is a document that was previously marked
12 at the last session of your deposition as
13 Dempsey Exhibit 2.

14 MR. BARKER: For those on
15 the phone, it begins with Bates
16 number JAN-MS-00060000953. And
17 it's a RACR report dated
18 October 20th, 2011.

19 BY MR. BARKER:

20 Q. Do you have Exhibit 2 in
21 front of you?

22 A. Yes, I do.

23 Q. Do you recall Mr. Janush
24 asking you questions about this document?

1 A. Yes, I do.

2 Q. And this document concerns a
3 meeting that you had in your capacity as
4 a Noramco employee with other Noramco
5 employees and the DEA, correct?

6 A. Yes.

7 Q. And that meeting took place
8 when?

9 A. October 20th, 2011.

10 Q. Okay. I don't want to go
11 over a lot of the ground that Mr. Janush
12 already covered, but I'll cover some
13 ground that he didn't. Did the DEA
14 request this meeting?

15 A. No.

16 Q. Then what was the purpose of
17 the 2011 meeting?

18 A. We -- we asked DEA if we
19 could come in and present the demand
20 signals, the forecasts we were receiving
21 from the customers as they -- this was
22 the timing that they were getting ready
23 to issue the next year's aggregate
24 production quota. And we wanted them to

1 see what our customers were saying what
2 they needed in terms of to support the
3 medical need as well as to support
4 validation and development volumes needed
5 for, like, the new innovators or anybody
6 that was doing a different formulation.

7 Q. And you used a term in
8 there, aggregate -- aggregate production
9 quota.

10 A. Yes.

11 Q. What is aggregate production
12 quota?

13 A. It's the total amount of
14 gram space active pharmaceutical
15 ingredient that can be manufactured in
16 the United States to support medical
17 research and exports.

18 Q. Okay. Does an API
19 manufacturer like Noramco need production
20 quota in order to make an opioid API?

21 A. Noramco needs manufacturing
22 quota to isolate and produce active
23 pharmaceutical ingredients.

24 Q. Okay. And how is

1 manufacturing quota different than
2 production quota?

3 A. The aggregate production
4 quota is the whole country volume. And
5 then individual book manufacturers get
6 pieces of the pie. And that's
7 manufacturing quota.

8 Q. Understood. So who
9 allocates manufacturing quota to Noramco
10 and other producers of opioid APIs?

11 A. DEA.

12 Q. And I guess we should define
13 another term we're using there, API.
14 What does API stand for?

15 A. Active pharmaceutical
16 ingredient.

17 Q. And is that a drug that
18 people can take, or is that something
19 different?

20 A. That's the raw powder that
21 goes into the formulation step.

22 Q. And who is Noramco selling
23 opioid API to?

24 A. To formulators or

1 manufacturers that make the pills, the
2 patches or the other -- the dosage.

3 Q. So Noramco doesn't sell to
4 any of the big wholesalers or
5 distributors, correct?

6 A. No.

7 Q. And Noramco doesn't sell
8 anything to pharmacies, correct?

9 A. No.

10 Q. Noramco doesn't sell
11 anything to doctors or hospitals,
12 correct?

13 A. No.

14 Q. Who makes the decision as to
15 how much manufacturing quota Noramco gets
16 in any given year?

17 A. DEA.

18 Q. Do Noramco's customers also
19 need a form of quota to buy opioid API
20 from Noramco?

21 A. They need procurement quota.

22 Q. How do they get that?

23 A. They have to submit a
24 request to DEA based on their sales and

1 their process losses. You know, when
2 they take the API and they formulate it,
3 it's not a one to one. So there is some
4 losses during the handling. So they will
5 go into DEA with their projected forecast
6 production. And ask for procurement
7 quota for the API to support their plan.

8 Q. And who makes the decision
9 as to how much procurement quota any of
10 Noramco's customers will get?

11 A. DEA.

12 Q. And could Noramco any amount
13 of API to whomever it wants?

14 A. No.

15 Q. What were the limits on what
16 API could sell -- excuse me.

17 What are the limits as to
18 what opioid API Noramco could sell?

19 A. Noramco could only sell API
20 a customer that has an active valid DEA
21 license and certificate of procurement
22 quota which tells us how much quota DEA
23 has given them. And we also, at the
24 time, Noramco did monthly report to DEA

1 how much we had shipped to all the
2 customers so DEA knew how much was going
3 to all those formulators.

4 Q. And DEA monitors that,
5 correct?

6 A. Yes.

7 Q. Can DEA adjust quota as the
8 year goes on?

9 A. There is a process where the
10 aggregate production quota can be
11 revised. The current year can be
12 revised. And it gets posted in a federal
13 register. And manufacturers can comment
14 on it if they see an increase in demand
15 where more quota is needed.

16 Q. Okay. Now, I want to take
17 you into the RACR itself and direct your
18 attention to the page ending in Bates
19 Number 957. Are you there?

20 A. Yes.

21 Q. And in particular, I want to
22 direct your attention to the paragraph a
23 little over halfway down. It reads, "Dr.
24 Sannerud" -- let me pause there.

1 Who is Dr. Sannerud?

2 A. Dr. Christine Sannerud was
3 the head of quota and the UN reporting
4 group at headquarters.

5 Q. So she was DEA?

6 A. Yes.

7 Q. Okay. So, "Dr. Sannerud of
8 the DEA was concerned that Noramco is
9 sole sourced from Turkey and Tasmania.
10 She was watching The Weather Channel the
11 other day, and was mentioning how
12 Tasmania climate would be changing in the
13 future. Bill assured her that we have
14 BCP and are looking at alternate regions
15 and even hemisphere. And Tasmania has
16 taken measures to ensure that it can
17 handle droughts, irrigation systems."

18 Did I read that correctly?

19 A. Yes.

20 Q. Okay. Who's Bill?

21 A. Bill Grubb.

22 Q. Okay. So Bill Grubb was
23 Noramco, correct?

24 A. Yea, he was. He was Noramco

1 sales and marketing.

2 Q. Okay. And what is BCP?

3 A. Business continuity plan.

4 Q. Okay. Was -- you were at
5 this meeting, correct?

6 A. Yes.

7 Q. In fact, you were the one
8 who wrote this note, right?

9 A. Yes.

10 Q. All right. Was the DEA
11 concerned that there was a time where
12 Noramco would not be able to produce
13 enough API opioid to satisfy the medical
14 need in the United States?

15 A. DEA was concerned that
16 should Turkey or Tasmania have weather
17 issues and the supply would be limited,
18 then we would not be able to procure
19 adequate narcotic raw materials to
20 support our quota grants in the medical
21 need.

22 Q. Did anybody from the DEA
23 suggest that you were asking for too much
24 manufacturing quota that year?

1 A. No.

2 MR. JANUSH: Objection.

3 BY MR. BARKER:

4 Q. Did Noramco get --
5 Noramco -- did Noramco get opioid API
6 manufacturing quota from the DEA for the
7 year after this, which would have been
8 2012?

9 A. Yes, we got manufacturing
10 quota.

11 Q. And who gave you that quota?

12 A. DEA.

13 Q. Did the DEA ever express a
14 concern that Noramco was producing too
15 much opioid API for the U.S.?

16 A. No.

17 Q. Let's go to another document
18 that Mr. Janush marked at the last
19 session of your deposition. It was
20 previously marked as Exhibit 4.

21 MR. BARKER: For those on
22 the phone, it begins with Bates
23 JAN-MS-00454956 and it runs
24 through 958.

1 BY MR. BARKER:

2 Q. Ms. Dempsey, do you recall
3 Mr. Janush asking you questions about
4 this document?

5 A. Yes, I do.

6 Q. Okay. And he didn't ask you
7 whether you ever received this e-mail?

8 A. No.

9 Q. Did you receive it?

10 A. No.

11 Q. Had you ever seen this
12 e-mail before he questioned you about it
13 at your deposition?

14 A. I don't recall, no.

15 Q. Okay. In questioning you
16 about this document, Mr. Janush had a
17 hypothetical about a customer who had
18 purchased a SKU for 50 milligrams of an
19 opioid product, and then one day decided
20 to purchase a 75-milligram SKU instead.

21 Do you remember that
22 hypothetical?

23 A. Yes, I do.

24 Q. Okay. Would the Janssen's

1 suspicious order monitoring system flag
2 that 75-milligram order?

3 A. Yes, it would.

4 Q. Why?

5 A. If the customer typically
6 ordered 50 milligrams, and then switched
7 and then ordered a 75-milligram, we'd
8 have no history. The 12-month rolling
9 average times three would be zero. And,
10 therefore, that order would have been
11 flagged as atypical requiring
12 investigation.

13 Q. Okay. And what if the
14 customer had ordered the 75-milligram
15 dose once before?

16 A. It still would have flagged
17 because one divided by 12, 52 weeks times
18 three is still a low volume.

19 Q. Okay. So in most cases
20 where a customer -- were a customer to be
21 switching SKUs to up the amount of opioid
22 in grams, it would get flagged because
23 it's a new SKU for that customer,
24 correct?

1 MR. JANUSH: Objection.

2 THE WITNESS: There was no
3 12-month consistent ordering
4 pattern for that SKU.

5 BY MR. BARKER:

6 Q. And even if they had a
7 history of having ordered a small amount
8 of that other SKU before, would it still
9 flag?

10 MR. JANUSH: Objection.

11 THE WITNESS: It was a
12 larger order, it would have.

13 BY MR. BARKER:

14 Q. Why?

15 A. Because it was exceeding the
16 three times the 52-week average.

17 MR. JANUSH: Objection.

18 BY MR. BARKER:

19 Q. And would this be the case
20 regardless of how many different SKUs
21 were placed in a single order?

22 A. The program goes by each
23 individual line item on the order, so
24 it's by SKU.

1 Q. Does the Janssen suspicious
2 order monitoring program ever look at
3 total orders by a customer and conduct an
4 analysis?

5 A. On a quarterly basis, we
6 take the entire volume of noncontrolled
7 products that we ship to the customers
8 along with all of the scheduled products
9 and do a comparison to see how much
10 percent control to non control they are
11 ordering.

12 Q. Okay. When you're looking
13 at that aspect of an order pattern, is
14 there a particular threshold that you're
15 looking at?

16 A. We like to generally see
17 more noncontrolled. We set up a
18 15 percent as an internal limit that
19 if -- should percent to CS go above
20 15 percent, we'd reach out and
21 investigate with the customer.

22 Q. And why did you set the
23 limit at 15 percent?

24 A. It was just based on what we

1 generally saw and thought would be a
2 significant -- and then recently DEA has
3 been reporting out that a typical
4 pharmacy should only be receiving
5 13 percent. So that sort of fell in line
6 with our 15 percent standard that we set
7 many years ago.

8 Q. Okay. And this analysis is
9 performed every quarter for every
10 customer, correct?

11 A. Yes. Every customer that
12 receives controlled substances.

13 Q. And what do you do if you
14 see a percentage of controlled substances
15 to non-controlled substances that's
16 higher than 15 percent?

17 A. We investigate.

18 Q. Okay. Would you ship it
19 unless your investigation cleared the
20 order as being reasonable?

21 A. Well, keep in mind that this
22 is only done every -- on a quarterly
23 basis and not set for each individual
24 order. But our current practice is that

1 if there is an order that is deemed
2 atypical, we have a standard process that
3 we look through and we do pull up what
4 was the last percentage CS to non-CS to
5 make sure that they're low.

6 Q. Okay. I'll next hand you
7 another document that was previously
8 marked at your deposition.

9 It was marked as Exhibit 16.
10 It begins with Bates JAN-MS-02963719 and
11 runs through 21.

12 Do you recall being asked
13 about this document at the last session
14 of your deposition?

15 A. Yes, I do.

16 Q. And Mr. Janush focused his
17 questioning on this sentence by my pen
18 which reads, "The most heavily purchased
19 product was Nucynta IR 50 milligrams
20 which had averages purchases" -- "average
21 purchases/sales of 324 bottles per week."

22 Did I read that correctly?

23 A. Yes.

24 Q. Do you recall that

1 questioning?

2 A. Yes.

3 Q. Well, let's put that in
4 context. He didn't ask you about the
5 sentence right before that, which reads?

6 A. "Sales of Schedule IIs
7 trended downward over this time period."

8 Q. Yes. He also didn't ask you
9 about the sentence right after that. Can
10 you read that one, please?

11 A. "Considering that Jupiter
12 Services, Southern Florida, and Walgreens
13 has 250-plus stores in the Miami/Fort
14 Lauderdale/Pompano Beach area alone, this
15 appears to be a reasonable figure."

16 Q. Now, I'm not that great at
17 fourth grade simple math, but 324 divided
18 by 250 would be roughly one and a quarter
19 bottle per store in a 250-plus store
20 area, correct?

21 A. Yes.

22 Q. And what was the conclusion
23 of the Janssen personnel who were looking
24 into the facts and circumstances here?

1 A. Well, I had asked for an
2 analysis to look at the recent data going
3 into this area to see if there was any
4 suspicious activity on our products. And
5 based on the fact that the C-IIs were
6 trending downward, and they reviewed all
7 the data and agreed that nothing -- the
8 next page, "I reviewed the data and agree
9 nothing seemed alarmed to us. We do not
10 believe the Jupiter DC was
11 overstocking/overpurchasing JOM
12 controlled substances based on the data
13 we found."

14 Q. Okay. And I've highlighted
15 that on the screen there.

16 Did you agree with that
17 conclusion?

18 A. Yes.

19 Q. Now, Mr. Janush also asked
20 you about another statement in this
21 document up at the top that says, "Mike
22 and I" -- who would Mike be in that
23 sentence?

24 A. Mike Levitt.

1 Q. Okay. So Mr. Levitt and
2 Mr. Martin fear that JOM is going to
3 reduce head count and there will not be
4 anyone left to do this kind of analysis
5 for them in the future.

6 Do you see that sentence?

7 A. Yes.

8 Q. Okay. Did JOM ever reduce
9 head count such that there was not anyone
10 left at the company to do this type of
11 analysis for you?

12 A. No, we continue to get this
13 type of analysis.

14 Q. I'm going to hand you what
15 was previously marked as Dempsey
16 Exhibit 5.

17 MR. BARKER: For those on
18 the phone, it begins with Bates
19 Number JAN-MS-03054480 and runs
20 through -- well, there's a native
21 document that's attached to it
22 apparently. The non-native runs
23 through 3054481.

24 BY MR. BARKER:

1 Q. So this is an e-mail that
2 related to the implementation of the
3 CSOS, C-S-O-S, system, correct?

4 A. Yes.

5 Q. You previously testified
6 that CSOS is only in place for the big
7 three distributors, McKesson, Cardinal
8 and ABC, correct?

9 A. Yes.

10 Q. Okay. Why was the CSOS
11 system put in place for only those three
12 distributors?

13 A. They requested it and they
14 had a higher volume of paper 222s.

15 Q. Than who?

16 A. Than the other customers.

17 Q. And was CSOS an electronic
18 system that Janssen created?

19 A. No. It was a DEA online
20 system.

21 Q. So it's the DEA's system,
22 not Janssen's system, correct?

23 A. Right.

24 Q. Okay. And CSOS, as you

1 said, is an electronic order processing
2 system, correct?

3 A. Yes.

4 Q. Okay. And even though
5 orders may be placed by the big three
6 distributors electronically, are those
7 orders still reviewed by the suspicious
8 order monitoring program at Janssen?

9 A. Yes.

10 Q. Was CSOS in any way an
11 end-run around the suspicious order
12 monitoring process?

13 A. No.

14 Q. What happens to an
15 electronically placed CSOS order when
16 it's received by Janssen?

17 A. Well, when it comes in from
18 the customer, our customer service has to
19 go in to an IT system that's -- that --
20 that'll show the electronic 222. And
21 just like the paper 222, customer service
22 has to review it for accuracy and make
23 sure there's no mistakes. If there's
24 mistakes, it has to go back to the

1 customer. If the 222 is accurate, then
2 it goes -- the order goes into SAP, and
3 it's placed on business manager hold,
4 just like the paper system.

5 Q. So are the same checks done
6 on a CSOS order that are done on an order
7 filed by a paper Form 222?

8 A. Yes.

9 Q. In or about 2013, were there
10 any enhancements made to Janssen's
11 suspicious order monitoring processes?

12 A. In 2013, we started monthly
13 compliance meetings, where we were
14 reviewing a set agenda, review our
15 metrics, orders, trends. And we also
16 revised all of the SOPs to make sure that
17 they reflect what we were currently
18 doing.

19 Q. Okay. And those monthly
20 meetings, were there minutes that went
21 with those?

22 A. Yes.

23 Q. Let's -- let's look at what
24 has been previously marked as Exhibit 10.

1 MR. BARKER: For those on
2 the phone, it begins with Bates
3 Number JAN-MS-00421188 and runs
4 through 91.

5 BY MR. BARKER:

6 Q. Do you recall Mr. Janush
7 asking you questions about this e-mail?

8 A. Yes.

9 Q. Okay. If you turn to the
10 page ending in Bates 90, is this an
11 example of minutes from a monthly
12 compliance meeting?

13 A. Yes.

14 Q. On that same page -- strike
15 that.

16 So this is part of your
17 suspicious order monitoring process, to
18 have regular meetings to consider current
19 events and to talk about things that
20 you're seeing in the ordering process,
21 correct?

22 A. Yes.

23 Q. So let's go down to the
24 Number 3, trend review.

1 It says there, "Walgreens
2 Perrysburg, Ohio, imminent suspension."

3 Do you see that?

4 A. Yes.

5 Q. You were at this meeting on
6 or about April 8th of 2013, correct?

7 A. Yes.

8 Q. All right. So what was --
9 what was this issue that's being
10 discussed in the Paragraph Number 3?

11 A. Well, there were some news
12 articles that were communicating that DEA
13 was going to be pulling the DEA license
14 for this Walgreens distribution center in
15 Ohio.

16 Q. Okay. And I don't see the
17 words "distribution center" there. How
18 do you know that's a distribution center?

19 A. Our trade confirmed that it
20 was the distribution center.

21 Q. Okay. So that's not an
22 individual pharmacy, correct?

23 A. No.

24 Q. Why did it matter to you

1 that a distribution center for Walgreens
2 potentially faced imminent suspension?

3 A. Because we wanted to make
4 sure that if they lost their license, our
5 product wasn't going to be shipped to it.

6 Q. And that particular
7 location, given that it was a
8 distribution center, also served multiple
9 individual pharmacies, correct?

10 A. Yes.

11 Q. Why is it that when you knew
12 Walgreens was under investigation, you
13 didn't immediately block orders of
14 controlled substances that Walgreens was
15 placing with Janssen?

16 A. Well, they never -- they
17 still had an active DEA license. And as
18 our previous discussion from 2007, DEA
19 told us that our rationale that, as long
20 as they have their license, patients need
21 medicine; therefore, we didn't stop our
22 shipments to the wholesaler that was --
23 that was distributing to this DC.

24 Q. Okay. And you're referring

1 to the advice that you got from DEA, or
2 rather the guidance, that you got from
3 DEA back in 2007 that we saw in
4 Exhibit 45, correct?

5 A. Yes.

6 Q. You also mentioned that SOPs
7 were revised in 2013. Let's talk about
8 those SOPs that were put in place.

9 I'm going to hand you five
10 documents.

11 MS. WINCKEL: Four and
12 actually --

13 MR. BARKER: Oh, that's
14 true.

15 BY MR. BARKER:

16 Q. So I'm going to hand you a
17 group of documents, four of which will be
18 marked as Exhibits 47-A through D, and
19 the fifth we're going to call it
20 Exhibit 40?

21 MS. WINCKEL: 37.

22 MR. BARKER: 37. Excuse me.
23 Because it was previously marked
24 by Mr. Janush.

1 (Document marked for
2 identification as Exhibit
3 Janssen-Dempsey-47-A.)

4 (Document marked for
5 identification as Exhibit
6 Janssen-Dempsey-47-B.)

7 (Document marked for
8 identification as Exhibit
9 Janssen-Dempsey-47-C.)

10 (Document marked for
11 identification as Exhibit
12 Janssen-Dempsey-47-D.)

13 BY MR. BARKER:

14 Q. So can you pull out
15 Exhibit 37 out from your pile of exhibits
16 there, or maybe the court reporter has
17 it.

18 A. 37?

19 Q. Yes. And then here are the
20 other ones, 47-A through D. Do you have
21 Exhibits 47-A through D and 37 in front
22 of you?

23 A. Yes, I do.

24 MR. JANUSH: Is A the one

1 ending in 34?

2 MR. BARKER: Yeah. Why
3 don't I identify them for the
4 record, just to keep it clear.

5 BY MR. BARKER:

6 Q. So Exhibit 47-A begins with
7 Bates JAN-MS-5457234 and runs through
8 7247.

9 47-B begins with
10 JAN-MS-03124146, runs through 4148.

11 Exhibit 47-C begins with
12 JAN-MS-03124141 and runs through 4145.

13 47-D is JAN-MS-03124088 and
14 it runs through 4100.

15 And Exhibit 37 that was
16 previously marked begins with
17 JAN-MS-03124101 and runs through 4110.

18 Okay. Do you have all those
19 in front of you?

20 A. Yes, I do.

21 Q. What is Exhibit 47-A?

22 A. 47-A is an SOP describing
23 the procedures to set up and create, and
24 maintain a customer master for any new

1 customers that JOM wants to ship product
2 to.

3 Q. And what's a customer
4 master?

5 A. Customer master data process
6 to set up a customer in SAP, so that we
7 can accept an order and process it. We
8 have to put the master data, which is all
9 the detailed information about the
10 customer, into SAP. And this --

11 Q. Okay. So this -- I'm sorry.

12 A. This tells us all the stuff
13 that we need from the customer in order
14 to fill out the master data fields.

15 Q. Okay. And was this
16 replacing another SOP?

17 A. It's Version 5. So I am
18 guessing it did. Yes.

19 Q. Let's go on to 47-B. What
20 is Exhibit 47-B?

21 A. Well, it is a job -- which
22 is a form, I'm guessing. Yeah, 47-A is
23 referencing this job, which is the
24 pre-application for new customers. So

1 this forms gets some of the preliminary
2 information required to set up a new
3 customer.

4 Q. Okay. And was this a new
5 form or was it replacing something else?

6 A. It appears to be a new
7 version, one -- a new form.

8 Q. And what is Exhibit 47-C?

9 A. After the application, this
10 is more detailed information on the
11 customer. So after it goes through an
12 internal review and a customer is
13 approved, they go and get more
14 information in regard around billing and
15 paying and shipping.

16 Q. Okay. What is Exhibit 47-D?

17 A. This is the SOP that is used
18 to monitor the licenses for the
19 customers.

20 Q. And that's a process for
21 checking that there's a valid license to
22 be ordering and receiving a controlled
23 substance?

24 A. Right.

1 Q. And what is the last one,
2 Exhibit 37?

3 A. It is the JOM customer
4 service suspicious and excessive order
5 SOP.

6 Q. Okay. And this is the
7 document --

8 A. I'm sorry. It's a work
9 instruction. A little bit more detail,
10 versus an SOP.

11 Q. Well, that's interesting.
12 Can you explain the difference between an
13 SOP and work instruction?

14 A. An SOP is usually -- it's
15 more high level, and it may detail
16 processes across more than one function.
17 So, you know, it may encompass more than
18 just one functional organization.

19 A work instruction is a
20 detailed work instruction that one group
21 is responsible -- limited few are
22 responsible for executing, and it gives
23 more of the detailed execution steps.

24 Q. And it's in Exhibit 37, the

1 work instruction, where we find the
2 definition of the current algorithm
3 threshold that states, at Paragraph 3.2,
4 "A potentially suspicious or excessive
5 controlled substance order can be defined
6 as the order that exceeds the minimum
7 order quantity requirements and is above
8 the three times (300%) of the calculated
9 12-month per week order average. This
10 definition also applies to products that
11 are scheduled in one or more states, but
12 not by the DEA."

13 Did I read that correctly?

14 A. Yes, you did.

15 Q. And is that the definition
16 of the threshold used by the algorithm in
17 the suspicious order monitoring process
18 at Janssen that is covered by this
19 particular work instruction?

20 A. Yes. That is the work
21 instruction definition in this SOP.

22 Q. Okay. Put those aside but
23 keep them handy.

24 Were the SOPs that we just

1 looked at, Exhibits 47-A through D, and
2 Exhibit 37, were they ever reviewed by
3 the DEA?

4 A. Yes.

5 Q. When was that?

6 A. In July of 2013.

7 Q. Okay. And in what context
8 were they reviewed?

9 A. During the inspection, we
10 provided an overview showing DEA a
11 process flow that took all these steps
12 and put it in a process flow, and then
13 provided them these SOPs during our
14 discussion of suspicious order
15 monitoring.

16 MR. BARKER: Okay. So let's
17 mark as Exhibit 48 a document
18 beginning JAN-MS-03123994, and
19 including the attachment, it runs
20 through 4005.

21 (Document marked for
22 identification as Exhibit
23 Janssen-Dempsey-48.)

24 BY MR. BARKER:

1 Q. Do you have Exhibit 48 in
2 front of you?

3 A. Yes, I do.

4 Q. Do you recognize it?

5 A. Yes, I do.

6 Q. What is it?

7 A. It is the daily notice of
8 inspection of DEA's visit at the end of
9 July of 2013.

10 Q. Okay. And is this another
11 one of the e-mail reports that are
12 standard practice to give after a DEA
13 inspection at a Janssen site?

14 A. It is a typical e-mail
15 notification for any regulatory body that
16 comes to inspect a J&J -- Janssen site,
17 but yes.

18 Q. Okay. And I won't belabor
19 this because we went over it before.
20 This type of an e-mail notice is
21 regularly prepared in the ordinary course
22 of business?

23 A. Yes.

24 Q. By someone who was present

1 and whose job it was to accurately take
2 notes of what happened, correct?

3 A. Yes.

4 Q. And these are maintained in
5 the ordinary course of business as well,
6 correct?

7 A. Yes.

8 Q. All right. So who's Martha
9 Wick?

10 A. She works in quality
11 assurance at the Kentucky distribution
12 center.

13 Q. Okay. And was it her job to
14 prepare this type of report at this point
15 in time?

16 A. She's typically the scribe
17 that attends inspections and writes down
18 what is discussed.

19 Q. When was this inspection?

20 A. It started on July 29, 2013.

21 Q. Okay. It was a two-day
22 inspection?

23 A. Yes.

24 Q. And she sent this notice on

1 July 30th of 2013, correct?

2 A. It looks like she sent this,
3 the final summary, at the end of the
4 entire e-mail chain, yeah.

5 Q. Okay. Were you present for
6 this inspection?

7 A. Yes, I was.

8 Q. And have you reviewed this
9 e-mail and notes in preparation for your
10 deposition?

11 A. Yes, I did.

12 Q. Do you believe that this
13 e-mail and the notes that are attached to
14 it are accurate?

15 A. Yes, I do.

16 Q. Okay. And for the record,
17 what I'm referring to is the notes,
18 because if we flip to page
19 JAN-MS-03123997, there is a document
20 that's entitled "Notes: DEA at KDC,"
21 correct?

22 A. Yes.

23 Q. And that is the attachment
24 to the e-mail that we're looking at, DEA

1 at KDC notes, correct?

2 A. Yes.

3 Q. Let's go to the attachment.

4 And in particular, I'd like you to turn
5 to Page 2 of the attachment. I'd like to
6 direct your attention to Point 13, which
7 says, "BL, suspicious orders?"

8 Okay. Does that mean
9 anything to you, "BL, suspicious orders?"

10 A. Right. So BL is Billy Lane.
11 He was the diversion investigator who was
12 leading the inspection. And he wanted to
13 discuss suspicious order process.

14 Q. Let's -- let's pause there
15 then. How many inspectors were there
16 that day?

17 A. This were two.

18 Q. Okay. And there is
19 Mr. Lane, we see back on the first page
20 of the report, right?

21 A. Yes.

22 Q. And then who is the other
23 inspector?

24 A. Jason Smith.

1 Q. He's listed here as well,
2 correct? All right.

3 So let's go back to the
4 attachment. It says underneath, "BL
5 suspicious orders," "A, GB, gave SOPs and
6 overview."

7 Does that mean anything to
8 you.

9 A. Guy Bacco was the customer
10 service supervisor, and he provided the
11 SOPs and the overview flow diagrams.

12 Q. Can you spell Mr. Bacco's
13 last name for the court reporter, please?

14 A. B-A-C-C-O.

15 Q. All right. And then there's
16 a list of items underneath there,
17 correct?

18 A. Yes.

19 Q. Okay. Were those the
20 suspicious order materials provided to
21 DEA at the time of the inspection?

22 A. Yes.

23 MR. JANUSH: Objection.

24 BY MR. BARKER:

1 Q. So let's come back to the
2 first item under there. Let's go to the
3 second item, the one that says, "DS-SOP
4 1251, JOM customer service, customer
5 master data process, V. 5.0, ED 23 July
6 2013."

7 Do you recognize that as an
8 identification of a particular document?

9 A. Yes.

10 Q. Is that one of the documents
11 that we previously marked as 47-A through
12 D or 37?

13 A. That document is 47-A.

14 Q. 47-A.

15 Let's go to the next item.

16 "DS-JOB 959, JOM customer
17 service new customer pre-application
18 Version 1, ED, 24 January, 2013."

19 Is that one of the SOPs that
20 we previously marked as 47-A through D or
21 37?

22 A. It's JOB Aid, which is 47-B.

23 Q. So let's go to the next
24 item, "DS-JOB 960. JOM customer service

1 new customer post application V. 1.0, ED
2 24 January, 2013.

3 Is that one of the documents
4 that we previously marked as Exhibit 47-A
5 through D or 37?

6 A. 47-C.

7 Q. Let's go to the next item,
8 "DS-WI 6049 license management SOP,
9 Version 1.0, ED 03 August, 2011."

10 Is that one of the documents
11 we previously marked?

12 A. 47-D.

13 Q. Okay. So it is
14 Exhibit 47-D, correct?

15 A. Yes.

16 Q. And the sixth item, "DS-WI
17 3824 JOM customer service suspicious or
18 excessive orders, Version 2.0, ED 24
19 July" -- it says 0213, but I think that's
20 probably a typo. Do you recognize that
21 as one of the documents that we
22 previously marked?

23 A. Yes.

24 Q. Which one is that?

1 A. 37.

2 Q. That leaves us with the
3 document at the top of the list there.
4 "JOM controlled substance order
5 processing, scope Schedule II to V and
6 include" -- it says say, but it's
7 probably state scheduled products, three
8 pages. Do you see that what that is?

9 A. That was an overview process
10 flow.

11 Q. Okay. Did you previously
12 see a copy of that document during your
13 deposition?

14 A. Yes. Those flow diagrams
15 are typically included in the training
16 decks when we -- when we train about our
17 suspicious order monitoring program.

18 Q. Okay. I'm going to hand you
19 a document that was previously marked at
20 your deposition as Exhibit 9. It's a
21 PowerPoint presentation that was produced
22 in native, so there aren't any Bates.

23 Do you have Exhibit 9 in
24 front of you?

1 A. Yes.

2 Q. And the item that is the
3 first item under the heading 13-A in the
4 notes that we were looking at is where in
5 this PowerPoint?

6 A. It's on Page 9. It starts
7 on Page 9.

8 Q. Starts on Page 9.

9 A. It's three pages, and it
10 shows the flow diagram.

11 Q. So it's the flowchart on
12 Pages 9, 10, and 11 of Exhibit 9?

13 A. Yes.

14 Q. And how do you know that's
15 the same document as what's described in
16 these notes?

17 A. Well, the title. And then
18 the date. And then I'm the one who
19 developed these.

20 Q. Developed these meaning --

21 A. Flow diagram. I -- the flow
22 diagrams.

23 Q. The flow diagram. Okay.

24 And when you say the title,

1 what are you referring to as the title?

2 A. The top of the flow diagrams
3 is "JOM controlled substance order
4 processing, scope Schedule II through V
5 and includes state scheduled products."

6 Q. Okay. So that's the same
7 title as what we saw in the other
8 document?

9 A. Mm-hmm.

10 Q. And these flow charts cover
11 one, two, three pages, right?

12 A. Yes.

13 Q. And in this flowchart, for
14 example, on the second page of it, it
15 shows the application of the algorithm
16 using the three times monthly -- weekly
17 average for each customer, correct?

18 A. Yes.

19 Q. And as we already covered
20 before, back in Exhibit 37, that same
21 standard is set forth at Paragraph 3.2,
22 correct?

23 A. Yes.

24 Q. Yes?

1 A. Yes.

2 Q. Okay. So let's turn back --
3 let's turn back to the inspection itself.

4 How long was this
5 inspection?

6 A. Two days.

7 Q. And how long each day?

8 A. I think she may have told
9 you when they showed up. I don't
10 remember the exact.

11 Q. Your best estimate?

12 A. They came at 8:30 and then
13 they'd leave after lunch.

14 Q. Okay.

15 A. So I think six hours a day.

16 Q. Six hours a day?

17 A. Yeah.

18 Q. For two days?

19 A. Yes.

20 Q. And did the DEA agents have
21 any comments on the suspicious order
22 monitoring materials that were provided
23 to them?

24 A. Well, as was recorded, there

1 were a few question -- Billy Lane had
2 questions, but Mike Levitt answered the
3 questions and reviewed the program.

4 Q. Are you looking on Page 3 of
5 the notes?

6 A. Yes.

7 Q. Let's go there. Where are
8 you looking?

9 A. At the top.

10 Q. Okay. Paragraph 14?

11 A. Yes.

12 Q. All right. So tell me what
13 happened.

14 A. So Billy Lane asked, "Is
15 there a sales rep that does a physical
16 visit to customers?" Mike Levitt says,
17 "Our customer base is just wholesalers,
18 not direct shipments to doctors or
19 pharmacies. 93-95 percent go to the big
20 three wholesalers. Program is based on a
21 new customer profile. We do a DEA check,
22 credit check, et cetera. Have enhanced
23 this program recently. We took
24 historical data and put it into a

1 database as a" --

2 Q. Pause there for a second.

3 So one of the things that he specifically
4 told them during this inspection was that
5 Janssen had enhanced its program
6 recently, taking historical information
7 and putting it into a database, correct?

8 A. Yes.

9 Q. And then they had a
10 question, right?

11 A. No, he didn't have --

12 Q. Oh, okay.

13 A. That wasn't DEA. That's --

14 Q. Then I'm -- go ahead.

15 Keep -- why don't you keep going there.
16 I'm sorry for interrupting.

17 A. So -- that's okay. So, "It
18 gives us more information, and we ask
19 additional questions if necessary. We
20 keep records of current programs. We
21 asked Billy Lane if it was necessary. As
22 far as the sales force, that would be our
23 trade group. We work with them if a
24 potential suspicious order, more in depth

1 now. We have a suspicious order
2 monitoring team that meets once a month,
3 looks for trends, et cetera. Has given
4 us more visibility with trade group.
5 Recently benchmarked with Purdue.
6 Additional training for sales group.
7 Recently" -- meaning the trade, the trade
8 folks -- "recently received information
9 from a sales group about a physician sent
10 to Martin Redd, and stopped shipping to
11 this customer."

12 Q. Okay. Why don't you pause
13 there. What does that mean?

14 A. In regards to Nucynta, we
15 received word from a sales team member
16 that they visited a physician where they
17 did not feel comfortable and they sensed
18 there was some suspicious activity going
19 on. And so we took the name, the
20 address, and we provided it to Kentucky
21 distribution -- sorry, Kentucky DEA,
22 Martin Redd. He was the leader at
23 Louisville DEA.

24 Q. Okay. So go ahead. Keep

1 going. What else were the agents told
2 about the suspicious order monitoring
3 process in addition to being provided
4 with all the documentation related to
5 that program?

6 MR. JANUSH: Objection.

7 THE WITNESS: "Guy Bacco's
8 group runs reports daily and may
9 call customers if necessary.
10 Sends report to DEA compliance
11 group. AD is Art Dysart,
12 "99 percent of what they review.
13 If a customer has not ordered in a
14 while and does, they will look at
15 it. Would like further direction
16 from DEA if any recommendation is
17 in general and especially for
18 suspicious order monitoring."

19 BY MR. BARKER:

20 Q. So at the end of the
21 discussion, Janssen specifically asked if
22 DEA had any recommendations in general or
23 especially for suspicious order
24 monitoring, correct?

1 A. Yes.

2 Q. Did DEA give any specific
3 advice relating to your suspicious order
4 monitoring program, including whether
5 there were any deficiencies or
6 improvements that could be made?

7 A. No. And if you look at the
8 end, in closing. He said no --

9 Q. You're saying the end.
10 Where are you looking?

11 A. Page 4.

12 Q. Page 4. Okay.

13 A. Closing.

14 Q. So what is the -- what is
15 closing? What are we talking about here?

16 A. This is what Billy Lane
17 said.

18 Q. Okay. Billy Lane is one of
19 the two DEA agents?

20 A. He was the lead inspector.

21 Q. Okay. So Mr. Lane told you
22 what?

23 A. "No violations of the
24 C.F.R." But he said the audit came out

1 fine.

2 Q. Okay. And again, as
3 Mr. Janush pointed out multiple times
4 before, the suspicious order monitoring
5 regulations are in the C.F.R.s, correct?

6 A. Yes.

7 Q. And then let's go to the top
8 of the next page too, please. It also
9 says, "No actions for their part."

10 Does that mean that there
11 were no violations or any other action
12 taken by the DEA?

13 A. That Billy Lane said that
14 they were not taking any actions.

15 Q. Okay. And BL is Billy Lane?

16 A. Yes.

17 Q. Okay. Did Billy Lane say
18 that he likes coming to facilities like
19 the Kentucky distribution center?

20 A. He says that, "Overall likes
21 coming to places like this."

22 Q. And did he have any comments
23 on your recordkeeping systems?

24 A. We had -- we asked him how

1 long we needed to maintain records. And
2 he was saying, "Keep everything in a
3 binder month by month and only required
4 to keep it for two years, although the
5 state, he thinks, may require five
6 years." And Guy Bacco said, "Seven years
7 from the J&J perspective."

8 Q. All right. I do have one
9 further question on this, Ms. Dempsey, if
10 you have a recollection. If you know.

11 What was this discussion
12 about here, "MG - who does report go to?
13 BL - we don't get a report."

14 A. When DEA comes to inspect a
15 location, they do prepare an inspection
16 report that goes up to headquarters. And
17 MG, Mike Griffith, he was like the
18 general manager, the head of operations
19 at the distribution center. And he was
20 asking, who does it go to. And he wanted
21 to know if we could get a copy of it.

22 Q. A copy of the DEA's internal
23 report --

24 A. Yes.

1 Q. -- about the inspection?

2 A. Yeah. And...

3 Q. And what the agents tell
4 you?

5 A. We don't get -- we don't get
6 a report.

7 MR. BARKER: I think we've
8 been going for a little more than
9 an hour.

10 MS. WINCKEL: Almost two.

11 MR. BARKER: All right. My,
12 how time flies. Do you want to
13 take a break now? Okay.

14 THE VIDEOGRAPHER: Remove
15 your microphones. The time is
16 3:48 p.m. Off the record.

17 (Short break.)

18 THE VIDEOGRAPHER: The time
19 is 3:59 p.m. Back on the record.

20 BY MR. BARKER:

21 Q. We're back from the break.
22 And before I move on, I want to go back
23 to this PowerPoint that was previously
24 marked as Exhibit 9.

1 When you were questioned
2 about Exhibit 9 before, Ms. Dempsey,
3 Mr. Janush asked you if you created this
4 deck.

5 Do you remember that?

6 A. Yes, I do.

7 Q. Did you create all the
8 slides in this deck?

9 A. No. I cut and pasted some
10 content from the DEA's presentations.

11 Q. Okay. And where are those?

12 A. Starting on Page 19 to the
13 rest.

14 Q. Okay. Page 19.

15 So from this Page 19 on,
16 these are not materials that you created,
17 correct?

18 A. No.

19 Q. And where did this portion
20 of the materials come from that we're
21 looking at right now on Page 19?

22 A. The slides from the October
23 DEA distributor conference.

24 Q. Who was the speaker?

1 A. I'm getting to that. It was
2 at the end. Page 35. Prevoznik
3 presented it at the 2013 distributor
4 conference.

5 Q. Okay. And Prevoznik is the
6 name we see right here?

7 A. Yes.

8 Q. And are there more slides
9 after this?

10 A. So this is the session that
11 I attended. But since DEA posts a lot of
12 their training content on the website, I
13 wanted to bring this ability to a slide
14 deck that Rannazzisi presented in
15 February of 2014 at a pharmaceutical
16 awareness meeting, which was just with
17 pharmacists. And that's what this Slides
18 36 to 47 covered.

19 Q. So 36, and that's by Joe
20 Rannazzisi?

21 A. Mm-hmm.

22 MR. JANUSH: Just for the
23 record, the date of Page 19 is
24 April 1, 2014. And the date

1 within the file name on Page 35 is
2 2013.

3 BY MR. BARKER:

4 Q. Okay. Is that consistent
5 with your recollection, that the file was
6 from 2014 and not 2013? He's referring
7 to, here, on Page 35, is what he's
8 referring to.

9 A. Right. The distributor
10 conference was in 2013. Yes.

11 Q. Was it in the fall of 2013?

12 A. I'd have to check. They had
13 three of them. I don't remember the
14 month.

15 Q. Okay. So that is consistent
16 with your recollection?

17 A. Mm-hmm.

18 Q. That this was a presentation
19 given in 2013?

20 A. Yes.

21 Q. Okay. Let's -- if you can
22 turn to Page 37. This is in that second
23 DEA slide deck that is part of Exhibit 9.

24 A. Yes.

1 Q. And this is a slide entitled
2 DEA distributor initiative, correct?

3 A. Yes.

4 Q. What was the distributor
5 initiative, to your understanding?

6 A. Do you want me to read the
7 slide?

8 Q. No. Do you have an
9 understanding as to what the DEA
10 distributor initiative was. You don't
11 need to read the slide.

12 A. From DEA conferences, the
13 way it was communicated is they were
14 inviting manufacturers and distributors
15 to headquarters to review their
16 suspicious order monitoring systems and
17 review company-specific ARCOS data for
18 the sales and purchases of controlled
19 substances, IIs and IIIs.

20 Q. Okay.

21 A. And the -- and as it says,
22 they also talked about trends involving
23 abuse of prescription controlled
24 substances.

1 Q. Okay. And was the -- it
2 says here that the distributor initiative
3 was going from August of 2005 to the
4 present, correct?

5 A. The present meaning 2014
6 when this was, yes.

7 Q. 2014. At least. Okay.
8 So that included the period
9 that you were inspected at the Kentucky
10 distribution center, and you provided
11 your suspicious order monitoring SOPs,
12 work instructions, and other materials to
13 the DEA agents, correct?

14 A. Yes.

15 Q. It mentions here that there
16 were briefings to 81 firms with 233
17 locations.

18 Do you have an understanding
19 as to what the briefings were that are
20 referred to on this slide as part of the
21 distributor initiative?

22 A. What I understood is exactly
23 what was up above, that they reviewed the
24 companies, the firms' suspicious order

1 monitoring system and ARCOS data. And
2 discussed the abuse of prescription
3 controlled substances.

4 Q. Did you have an
5 understanding as to whether any
6 distributors or manufacturers were asked
7 to come to Washington to have specific
8 meetings with the DEA?

9 A. DEA was communicating that
10 they did ask distributors and
11 manufacturers to come to Washington for
12 these briefings.

13 Q. Okay. And do you have an
14 understanding as to why some companies
15 were called to Washington and others were
16 not?

17 MR. JANUSH: Objection.

18 THE WITNESS: I think the
19 focus of these initiatives were on
20 the national trends involving
21 abuse of prescription drugs. It
22 was focused on Schedule IIs and
23 IIIs that were being abused. So
24 they were the firms that were

1 focused on.

2 BY MR. BARKER:

3 Q. Focused on by the DEA?

4 A. Mm-hmm.

5 Q. Was Janssen called to
6 Washington as part of the distributor
7 initiative to have meetings with the DEA?

8 A. No.

9 Q. Was Noramco called to
10 Washington to have meetings with the DEA
11 as part of the distributor initiative?

12 A. No.

13 Q. Was any J&J company, to your
14 knowledge, called to Washington to meet
15 with the DEA about the issues that were
16 involved in the distributor initiative?

17 A. No.

18 Q. So the only contacts that
19 Janssen had were with the DEA agents
20 responsible for its specific facilities,
21 correct?

22 A. Yes.

23 Q. Let's go back to the
24 timeline of inspections of Janssen's

1 distribution centers.

2 Was the Janssen distribution
3 center in Kentucky inspected after 2013?

4 A. Yes. Routinely.

5 MR. BARKER: We're going to
6 mark as Exhibit 49, another
7 document beginning with Bates
8 Numbers JAN-MS-02984602 and
9 running through 84607.

10 (Document marked for
11 identification as Exhibit
12 Janssen-Dempsey-49.)

13 BY MR. BARKER:

14 Q. Do you have Exhibit 49 in
15 front of you?

16 A. Yes.

17 Q. And directing your attention
18 to the bottom of the page. We have an
19 e-mail that begins on the first page that
20 is coming from Martha Wick, right?

21 A. Yes.

22 Q. And she's the same person
23 that we saw prepared the last report,
24 correct?

1 A. Yes.

2 Q. And it's part of her job to
3 prepare these types of reports in the
4 ordinary course of business, correct?

5 A. Yes.

6 Q. All right. And this one is
7 dated January 28th, 2015?

8 A. Yes.

9 Q. And it continues on the next
10 page. When was this particular
11 inspection that where we were talking
12 we -- looking at -- strike that.

13 When did the inspection take
14 place that was the subject of this
15 report?

16 A. It looks like it was
17 January 28th, 2015.

18 Q. You see that from the
19 subject line of the report?

20 A. No. I see it from the body.
21 She has a typo.

22 Q. Oh, date 28 January?

23 A. Yeah. She wasn't quite used
24 to 2015. It was January.

1 Q. Got it. So the subject
2 line, although it says 28 January, 2014,
3 it's actually 2015 --

4 A. Yes.

5 Q. -- as reflected in the body.

6 Okay. And at the top line
7 it says, "The DEA just left, there were
8 no observations."

9 What does that tell you
10 about this particular inspection?

11 MR. JANUSH: Objection.

12 MR. BARKER: Strike that.

13 BY MR. BARKER:

14 Q. Do you have an understanding
15 of what the result of the inspection was
16 on or about January 28th of 2015?

17 A. As it's explained here, that
18 from the time period that they audited,
19 which was August 18, 2014, through that
20 January, all the documentation and all
21 the processes they reviewed, there was --
22 there were no observations. Everything
23 was good.

24 Q. Okay. And if we go to Page

1 605, we see a brief inspection summary of
2 the day before, correct?

3 A. Yes.

4 Q. That's for January 27th?

5 A. Mm-hmm.

6 Q. And beginning on that page
7 and continuing onto the next there's a
8 list of attendees at the bottom, right?

9 A. Mm-hmm.

10 Q. If we can get that
11 straightened out. Attendees. Who is
12 Mike G.?

13 A. Mike Griffith.

14 Q. Who is Kevin P.?

15 A. Kevin Pedergast.

16 Q. Joe C., who is that?

17 A. Hmm. It's been a while. I
18 have to find out. I don't recall who
19 that is.

20 Q. Okay. And -- well, let me
21 ask a different question. There were a
22 number of Janssen people present,
23 correct?

24 A. Yes.

1 Q. Okay. And who were the
2 investigators from the DEA?

3 A. As you looked up before,
4 there were three. You had Pat Sowers,
5 Jason Smith again, and Chris Skaggs.

6 Q. And when we go to the next
7 page, one of the requests of this
8 inspection, just like in 2013 was for
9 suspicious order procedures, correct?

10 A. Yes.

11 Q. Did you provide those
12 suspicious order procedures materials to
13 the DEA agents who were inspecting the
14 Kentucky facility?

15 A. Yes.

16 Q. And were those the current
17 SOPs that were provided?

18 MR. JANUSH: Objection.

19 THE WITNESS: The SOPs that
20 were effective at the date of the
21 inspection were provided.

22 BY MR. BARKER:

23 Q. Now, again, going back to
24 the previous page. It says there were no

1 observations, correct?

2 A. Yes.

3 Q. Okay. And if we look
4 further down on that same page. It says,
5 "Open discussion points, none
6 identified," correct?

7 A. Yes.

8 (Brief interruption.)

9 THE VIDEOGRAPHER: The time
10 is 4:12 p.m. Off the record.

11 (Brief pause.)

12 THE VIDEOGRAPHER: Okay. We
13 are back on the record. The time
14 is 4:24 p.m.

15 BY MR. BARKER:

16 Q. We had to go off the record
17 there briefly due to a technical issue,
18 but we're back.

19 And we were talking about
20 Exhibit 49, the inspection of the Janssen
21 Kentucky distribution center on or about
22 January 27th and 28th, 2015.

23 When that -- after that
24 inspection was over, did DEA follow up

1 with the Kentucky distribution center
2 with any comments, positive or negative,
3 about its suspicious order monitoring
4 program?

5 A. No.

6 Q. Were there any other
7 inspections of Janssen DCs in 2015?

8 A. There was most likely,
9 because we had two DCs, so there probably
10 was another inspection. I don't know of
11 the year. But the DEA goes to both DCs
12 on a regular basis, every two to
13 three years.

14 MR. BARKER: Let's mark as
15 Exhibit 50.

16 (Document marked for
17 identification as Exhibit
18 Janssen-Dempsey-50.)

19 MR. BARKER: A one-page
20 document bearing Bates Number
21 JAN-MS-05433741.

22 BY MR. BARKER:

23 Q. Ms. Dempsey, do you
24 recognize this as another e-mail report

1 of an inspection at a Janssen
2 distribution center?

3 A. It appears to me to be a
4 notes that were taken during the DEA
5 inspection.

6 Q. And when you say there were
7 notes taken, are you talking about the
8 e-mail from Robert Helfrick?

9 A. Yes.

10 Q. Dated August 4th, 2015,
11 right?

12 A. Yes.

13 Q. And these are -- and who is
14 Robert Helfrick?

15 A. He was the QA manager over
16 both distribution centers.

17 Q. Okay. And what do these
18 notes relate to?

19 A. It is his notes that he took
20 during a DEA inspection.

21 Q. Okay. And where was this
22 inspection?

23 A. Based on the fact of some of
24 the people involved and FDC.

1 So a percent of total
2 business of controlled substances being
3 shipped out of FDC. I'm going to say it
4 was the Franklin distribution center.

5 Q. Okay. And you're looking at
6 this right here?

7 A. Yes.

8 Q. Correct?

9 A. Yes. And above it says too,
10 "DEA Form 222 associated with the
11 distributor registration materials
12 received in/shipped out of FDC."

13 So the scope of the
14 inspection was from January 21, 2015, to
15 August 4, 2015.

16 Q. Okay. And is it a standard
17 practice for a quality assurance manager
18 like Mr. Helfrick to take notes at these
19 types of inspections?

20 A. Typically, quality leads the
21 inspection and somebody in quality
22 assurance does take notes.

23 Q. Can you tell from this
24 report whether the suspicious order

1 monitoring SOPs were provided to the DEA
2 inspectors for this inspection?

3 MR. JANUSH: Objection.

4 THE WITNESS: If you look at
5 the list of requests and
6 activities, you can see what was
7 provided and what wasn't to be
8 provided, and it looks like at the
9 end, a copy of suspicious order
10 SOP.

11 BY MR. BARKER:

12 Q. And that's right here?

13 A. Yes.

14 Q. All right. And where is the
15 Franklin distribution center located?

16 A. New Jersey.

17 Q. New Jersey. And so, was
18 this a different group of DEA agents who
19 were doing the inspection?

20 A. Yes. Our Franklin
21 distribution center falls under the
22 Newark district for DEA.

23 Q. And are you aware of any
24 comments, positive or negative, about the

1 suspicious order monitoring SOPs that
2 were provided to the Newark office of the
3 DEA?

4 A. No. No comments that I
5 recall.

6 MR. BARKER: Let's mark as
7 Exhibit 51 a two-page document
8 beginning with Bates
9 JAN-MS-05433744 going onto 3745.

10 (Document marked for
11 identification as Exhibit
12 Janssen-Dempsey-51.)

13 BY MR. BARKER:

14 Q. Do you have Exhibit 51 in
15 front of you?

16 A. Yes.

17 Q. Okay. Do you recognize it?

18 A. Yes.

19 Q. What is it?

20 A. It was an e-mail I received
21 in regards to the unannounced DEA
22 inspection at the Franklin distribution
23 center.

24 Q. And is that the same

1 inspection that you were just looking at
2 in Exhibit 50?

3 A. The dates match.

4 Q. And what was the result of
5 that inspection by the New Jersey
6 Newark -- strike that.

7 What was the result of the
8 inspection by the Newark, New Jersey
9 office of the DEA at the Franklin
10 distribution center?

11 A. There were zero
12 observations.

13 Q. Okay. You're seeing that
14 here?

15 A. Yes.

16 Q. And what does zero
17 observations mean?

18 A. They did not find any
19 noncompliance during their audit of the
20 FDC.

21 Q. When was the next inspection
22 that occurred of a Janssen facility that
23 you're aware of?

24 A. I am guessing two years

1 after.

2 Q. After 2015?

3 A. Yes.

4 Q. So 2017?

5 A. Yes. Especially since KDC
6 said that the -- at the last KDC, that
7 the DEA said they'd be back in two years.

8 Q. So let's mark as Exhibit 52
9 a document beginning with JAN-MS-0412006
10 through 4009.

11 (Document marked for
12 identification as Exhibit
13 Janssen-Dempsey-52.)

14 BY MR. BARKER:

15 Q. Do you have Exhibit 52 in
16 front of you?

17 A. Yes, I do.

18 Q. And for the record
19 Exhibit 52 is a two-page e-mail followed
20 by a two-page attachment, correct?

21 A. Yes.

22 Q. Okay. And this e-mail is
23 again from Mr. Helfrick, correct?

24 A. Yes. Yep.

1 Q. He's a manager, correct?

2 A. Yes.

3 Q. And his -- part of his job
4 is to prepare reports of inspections,
5 correct?

6 A. Yes.

7 Q. And he prepares those
8 reports at or about the time of the
9 inspection in the ordinary course of
10 business, correct?

11 A. Yes.

12 Q. And those reports are
13 maintained in the ordinary course of
14 business, correct?

15 A. Yes.

16 Q. Okay. So what inspection
17 does this report relate to?

18 A. It was the three-year
19 inspection on importer/exporter for
20 Kentucky distribution center.

21 Q. Okay. So it's the Kentucky
22 distribution center again?

23 A. Yes.

24 Q. And who were the inspectors

1 this time?

2 A. B. Morgan Freeman and Carl
3 O. Maskew.

4 Q. And were they from the DEA?

5 A. Yeah. Louisville, Kentucky
6 DEA.

7 Q. Was there a discussion of
8 suspicious order monitoring protocols at
9 this inspection?

10 A. According to Rob in his
11 notes, he said there was.

12 Q. And where do you see that?

13 A. On the first page.

14 Q. Okay.

15 A. "As an FYI, there was a
16 discussion on suspicious order monitoring
17 process."

18 Q. Okay. And if we look at the
19 attachment -- and you see there's a --
20 the attachment is indicated here. It's a
21 regulatory inspection, importer/exporter
22 checklist.

23 A. Mm-hmm.

24 Q. Right. So we go to the

1 attachment. And that's a regulatory
2 inspection, importer/exporter checklist,
3 right?

4 A. Mm-hmm.

5 Q. And let's look down at
6 number 15.

7 Is it the case that what the
8 DEA inspectors who visited the Kentucky
9 distribution facility on or about
10 December 20th of 2017 wanted to see all
11 written policies or procedures pertaining
12 to controlled substances; i.e., standard
13 operating procedures, and to include due
14 diligence for new customers and new
15 patients?

16 A. Yes.

17 MR. JANUSH: Objection.

18 BY MR. BARKER:

19 Q. Okay. Were those materials
20 provided to the DEA inspectors?

21 MR. JANUSH: Objection.

22 THE WITNESS: I can't tell
23 from this document if it was. But
24 it looks like it was asked for.

1 Just the DEA didn't finish filling
2 it out.

3 BY MR. BARKER:

4 Q. And you are referring to the
5 attachment here in that it doesn't say
6 anything in this box. Is that what
7 you're saying?

8 A. Yes, yes.

9 Q. Okay. All right.

10 MR. BARKER: Let's mark as
11 the next exhibit. Exhibit 53.

12 (Document marked for
13 identification as Exhibit
14 Janssen-Dempsey-53.)

15 MR. BARKER: Exhibit 53 for
16 the record that begins at Bates
17 JAN-MS-05433730 and runs through
18 3740.

19 BY MR. BARKER:

20 Q. Do you have Exhibit 53 in
21 front of you?

22 A. Yes.

23 Q. No, hang on.

24 MR. BARKER: Can I have that

1 back, please?

2 MS. WINCKEL: No, that's it.

3 MR. BARKER: That's it?

4 MS. WINCKEL: Remember, this
5 is the new one.

6 MR. BARKER: Oh, right.

7 Thank you. My mistake.

8 BY MR. BARKER:

9 Q. And Exhibit 53 is an e-mail
10 from Mr. -- from Mr. Helfrick, who we saw
11 on Exhibit 52, correct?

12 A. Mm-hmm.

13 Q. Who was running the meeting
14 with the DEA. He is e-mailing to two
15 folks, Carl Maskew and Brittany Freeman,
16 both at DOJ. And again from 52, those
17 were the investigators?

18 A. Mm-hmm.

19 Q. And he's e-mailing this the
20 same day as the inspection, correct?

21 A. Yes.

22 Q. December 20th, 2017. And
23 his e-mail reads, "Hi, Morgan and Carl.
24 It was a pleasure to meet both of you

1 today. Attached is our local procedure
2 on suspicious and excessive order
3 monitoring. Also I've added my contact
4 information below."

5 Do you see that?

6 A. Yes.

7 Q. Did I read it correctly?

8 A. Yes.

9 Q. Okay. Does that refresh
10 your recollection as to whether a
11 suspicious order monitoring protocol was
12 provided to the DEA during the
13 December 20th, 2017, inspection of the
14 Kentucky distribution facility?

15 MR. JANUSH: Objection.

16 THE WITNESS: Yes.

17 BY MR. BARKER:

18 Q. It does?

19 A. Yes.

20 Q. Okay. And was -- was it
21 provided?

22 MR. JANUSH: Objection.

23 THE WITNESS: Based on the
24 attachment, it's a PDF that was

1 attached to the e-mail.

2 BY MR. BARKER:

3 Q. Right. And so -- and you're
4 referring to the attachment right here.
5 It says suspicious and excessive order
6 procedure.PDF, right?

7 A. Yes.

8 Q. And then we go to it. And
9 that's right here. It's the work
10 instruction, correct?

11 A. Yes.

12 Q. After Mr. Helfrick provided
13 the DEA Investigators Freeman and Maskew
14 with a copy of the suspicious order
15 monitoring protocol, did you hear
16 anything more from DEA?

17 A. On the SOP, no.

18 Q. About anything? Did you
19 hear anything more from DEA about that
20 inspection?

21 A. If I recall, they came back
22 again to do the distributor.

23 Q. Oh, okay. Well, let's mark
24 another exhibit, and we'll get to that.

1 But let me -- let me ask you
2 the more narrow question, which is did
3 you hear back from them about the
4 suspicious order monitoring materials
5 that you had provided to them?

6 MR. JANUSH: Objection.

7 THE WITNESS: No.

8 MR. JANUSH: Are you
9 representing that this witness
10 provided? You keep using the word
11 "you."

12 THE WITNESS: JOM.

13 MR. BARKER: Well, fair
14 enough, that it was provided by
15 the company.

16 BY MR. BARKER:

17 Q. So I should say, did you
18 ever hear back from DEA regarding the
19 monitoring materials that Janssen had
20 provided to them at the inspection of the
21 Kentucky distribution facility on or
22 about December 20th, 2017?

23 MR. JANUSH: Objection.

24 THE WITNESS: Rob did not

1 communicate that he had any
2 response from DEA.

3 BY MR. BARKER:

4 Q. Okay. And certainly not
5 part of his report, which we saw here in
6 Exhibit 52, correct?

7 A. Right.

8 Q. The result of the inspection
9 was what?

10 A. Zero observations.

11 Q. Zero observations. Meaning
12 that they had no criticisms or
13 corrections for your distribution
14 facility, correct?

15 A. Correct.

16 Q. I'm going to mark as the
17 next exhibit a document beginning Bates
18 JAN-MS-03124010 going through 4011.

19 MR. BARKER: We're marking
20 this as Exhibit 54.

21 (Document marked for
22 identification as Exhibit
23 Janssen-Dempsey-54.)

24 BY MR. BARKER:

1 Q. Do you have Exhibit 54 in
2 front of you?

3 A. Yes.

4 Q. Do you recognize it as
5 another inspection report prepared by
6 Mr. Helfrick --

7 A. Yes.

8 Q. -- in the ordinary course of
9 business?

10 Okay. And to what
11 inspection of the Kentucky distribution
12 center does this report relate?

13 A. It covers the three-year
14 inspection on the distributor.

15 Q. And it's the same facility,
16 right? It's the Kentucky distribution
17 center, correct?

18 A. Mm-hmm, yes.

19 Q. Okay. And it's the same two
20 agents?

21 A. No. No.

22 Q. Oh, you're right?

23 A. Same leader.

24 Q. Same leader. Okay. Thank

1 you for correcting me. Who was the lead
2 investigator?

3 A. B. Morgan Freeman.

4 Q. And who is the other
5 investigator this time?

6 A. Jason Smith.

7 Q. The same one who had been
8 there in 2013, right?

9 A. Yes.

10 Q. Okay. And so this was eight
11 days after the SOP had been provided by
12 Mr. Helfrick, as we saw in Exhibit 53,
13 correct?

14 A. Correct.

15 Q. He provided that on the
16 20th. And now they are back on the 28th?

17 A. Yes.

18 Q. Were there any issues found
19 by the DEA in its follow-up inspection on
20 December 28th of 2017 at the Kentucky
21 distribution center?

22 A. Going to the summary, there
23 were zero observations, no issues.

24 Q. So again, they had no

1 criticisms or comments on what they had
2 been provided, correct?

3 A. Correct.

4 MR. BARKER: Next document
5 that I'm going to provide you was
6 one previously marked at your
7 deposition as Exhibit 19.

8 BY MR. BARKER:

9 Q. It begins with
10 JAN-MS-2987651, running through 7656.

11 Do you have Exhibit 19 in
12 front of you?

13 A. Yes, I do.

14 Q. Do you recall Mr. Janush
15 questioning you about this document?

16 A. Yes, I do.

17 Q. Okay. So I want to direct
18 your attention to the second page of the
19 document. And to the comment for DM-3.
20 Are you DM-3 for purposes of this
21 document?

22 A. Yes.

23 Q. How do you know that?

24 A. It's Dempsey, Michele. My

1 initials.

2 Q. All right. And you write in
3 this document -- well, let's back up
4 here.

5 What are you commenting on?

6 A. We held a workshop in
7 December of 2017. It was
8 cross-functional. We had people from
9 quality and commercial, and IT, customer
10 service, plant -- we had a
11 cross-functional team. And we were going
12 through our current process for the whole
13 program and identifying opportunities.
14 And we were discussing about the
15 algorithm and the fact that it's only run
16 once a day, and that EDIs come around the
17 clock.

18 Q. Okay. You are also talking
19 about the current monitoring report is
20 based on the three times the customer's
21 12-month rolling weekly average of
22 shipments, correct?

23 A. Yes.

24 Q. And you're talking about the

1 potential enhancements that can be made
2 to that system as recommended by
3 Mr. Woodworth and DCAG, correct?

4 A. This is when we were
5 initially discussing the opportunity.
6 This is before the report.

7 Q. One of the workshop
8 attendees was Mr. Woodworth, correct?

9 A. Yes. Yes, yes.

10 Q. Okay. So on that topic, can
11 you read what your comment was?

12 A. "Anytime we need to have a
13 review done each morning by personnel
14 leads to potential of error, the
15 correct" -- "the current remediation is
16 not the perfect" -- "not the preferred
17 long-term" -- "long-time solution."

18 Q. Okay. What is it about the
19 current process that could lead to error?

20 A. It is manually intensive,
21 requiring a person to do activity.

22 Q. Would it be better if you
23 could get a computer to do that activity?

24 A. Yes.

1 Q. Just like in 2005, you
2 upgraded to a computer system that did
3 the stuff that you were doing manually
4 before, correct?

5 A. Correct.

6 Q. Okay. Does someone have to
7 manually hold back the order until the
8 suspicious order monitoring protocol is
9 executed?

10 A. Any controlled substance
11 order that is put into SAP goes in this
12 business manager hold, and someone
13 physically have has to go into SAP and
14 release it after all the processing is
15 done.

16 Q. So all the orders are
17 automatically held, and they have to be
18 manually released, correct?

19 A. Yes, yes, yes.

20 Q. Now, let's look at third
21 item on this page. It reads, "Current BW
22 report algorithm measures orders by NDC
23 number, SKU, not drug class, total
24 fentanyl, for example, or consolidated

1 customer, just ship-to address, and total
2 brand base of controlled substance to the
3 consolidated or individual registrant."

4 Okay. Now, this is the
5 potential issue and enhancement that
6 Mr. Janush spent a lot of time talking to
7 you about in this deposition, correct?

8 A. Yes.

9 Q. Okay. And previously you
10 tried to explain to him what the issue
11 was.

12 Let's look at your comment
13 over on the right-hand side.

14 MR. JANUSH: Object to the
15 narrative.

16 MR. BARKER: Okay. We'll
17 strike the narrative.

18 BY MR. BARKER:

19 Q. I want to -- on this topic,
20 I want to direct your attention to the
21 comment SB-4. Who is making this
22 comment?

23 A. Brian Strehlke.

24 Q. And Brian Strehlke works

1 with you, correct?

2 A. Yes, yes.

3 Q. And what does Mr. Strehlke
4 say?

5 A. "Considering drug class and
6 customer locations should go a long way
7 towards eliminating false positives in
8 the report."

9 Q. Okay. And what's he talking
10 about there?

11 A. He's talking about when we
12 had -- as I explained earlier today, if a
13 customer only orders one SKU once a year,
14 when it's time for them to reorder, they
15 automatically come up as a flagged order
16 and per our process, we have to
17 investigate, document the investigation,
18 and then -- prior to releasing it.

19 Q. And right below
20 Mr. Strehlke's comment is another comment
21 from you. That's DM, right?

22 A. Yes.

23 Q. And what's your comment?

24 A. "Agree, can't tell you how

1 many investigations are done because a
2 customer hasn't ordered a particular
3 strength in the last 12 months."

4 Q. Okay. And is this what you
5 were trying to explain to Mr. Janush
6 before, that the improvement of moving
7 from a SKU-based system to a brand-based
8 system would reduce the number of
9 potentially questionable orders that you
10 had to investigate?

11 MR. JANUSH: Objection.

12 THE WITNESS: It would
13 eliminate the false positives so
14 that the orders that we do see
15 would be the ones that are truly
16 suspicious and not based on the
17 ordering pattern of the customer.

18 BY MR. BARKER:

19 Q. Well, you mean truly
20 potentially suspicious, correct?

21 A. Right.

22 Q. Because until you complete
23 your investigation, you don't know
24 whether they are suspicious?

1 A. Agreed.

2 Q. Were any of the improvements
3 that were being discussed at this meeting
4 or in Mr. Woodworth's report from the
5 group DCAG about improving the system so
6 that you would catch orders that were
7 potentially suspicious that were possibly
8 being missed?

9 A. No.

10 Q. Okay. Were there additional
11 updates to Janssen's suspicious order
12 monitoring program in 2017 and 2018?

13 A. Well, after receiving the
14 recommendations from DCAG we did
15 implement some changes to address some of
16 the recommendations enhancing our
17 program. So there were SOP changes, an
18 introduction of a customer form to fill
19 out when we do have questionable orders.

20 Q. Okay. And let's talk about
21 Mr. Woodworth, right?

22 A. Yes.

23 Q. Were you the one that hired
24 Mr. Woodworth and his group, the Drug and

1 Chemical Advisory Group?

2 A. I was involved with the
3 selection of him, to bring him in, yes.

4 Q. Was -- and if I refer to
5 that as DCAG for short, would you
6 recognize that as the Drug and Chemical
7 Advisory Group?

8 A. Drug and Chemical
9 Advisory -- yes.

10 Q. Were you familiar with the
11 drug and chemical advisory group?

12 A. Yes.

13 Q. I'm going to hand you a
14 document that we marked as Exhibit 55
15 which are the bios of the DCAG principals
16 that were pulled off of their website.

17 (Document marked for
18 identification as Exhibit
19 Janssen-Dempsey-55.)

20 BY MR. BARKER:

21 Q. You testified before that
22 you knew about DCAG before you hired
23 them?

24 A. Yes.

1 Q. And how -- how do you know
2 the principals of DCAG?

3 A. When I was working for
4 Noramco, I know that Terry Woodworth and
5 Frank Sapienza had provided guidance to
6 the Noramco company. So that's how I
7 knew them.

8 Q. Okay. And their bios are
9 briefly stated on the second page of
10 Exhibit 55, correct?

11 A. Well, Frank Sapienza starts
12 on the bottom of the first page.

13 Q. It does. You're absolutely
14 right, even though his picture is on the
15 next page. It starts -- starts here.

16 And did you review their
17 qualifications before you hired them?

18 A. For suspicious order
19 monitoring, no.

20 Q. But did you have an
21 understanding as to whether either of
22 them had a background with the DEA
23 before --

24 A. Yes.

1 Q. -- you hired them?

2 A. Yes. I knew from my
3 experience at Noramco that they were
4 retired headquarter DEA employees with
5 experience and knowledge of the
6 regulations.

7 Q. Okay. And, in fact,
8 Mr. Sapienza was a former chief of the
9 drug and chemical evaluation section of
10 the DEA office of diversion control,
11 correct?

12 A. Yes.

13 Q. And Mr. -- Mr. Woodworth was
14 deputy director in the DEA office of
15 diversion control, correct?

16 A. Yes.

17 Q. You thought that these
18 gentlemen would be knowledgeable about
19 diversion issues and suspicious order
20 monitoring, correct?

21 MR. JANUSH: Objection.

22 THE WITNESS: Yes.

23 BY MR. BARKER:

24 Q. Let's talk about the report

1 that was generated by the DCAG group.

2 MR. JANUSH: Which one?

3 MR. BARKER: That's not --
4 there were multiple -- was that an
5 objection, sir?

6 MR. JANUSH: I'm asking
7 which one so that I know which
8 ones to pull up.

9 MR. BARKER: You'll know
10 when I give you an exhibit number.

11 MR. JANUSH: All right.

12 BY MR. BARKER:

13 Q. If you pull out from your
14 stack of exhibits over there from earlier
15 today, pull out Exhibit 26. Do you have
16 Exhibit 26 in front of you?

17 A. I do.

18 Q. We previously went over
19 that. This was the initial draft of the
20 report provided by Mr. Woodworth --
21 Woodworth, excuse me, correct?

22 A. Correct.

23 Q. And I want you to turn to
24 Page 2, and direct your attention to the

1 full paragraph at the bottom.

2 A. Yes.

3 Q. And what was DCAG's ultimate
4 conclusion about Janssen's suspicious
5 order monitoring system, in the initial
6 draft of its report?

7 A. The DCAG evaluation found
8 that the suspicious orders monitoring
9 program for the JOM site in
10 Shepherdsville, Kentucky complies with
11 the DEA requirements set forth in the
12 federal regulations, Title 21 Code of
13 Federal Regulations, C.F.R. section
14 1301.74 (b) .

15 Q. And those were sections of
16 the C.F.R. that Mr. Janush showed you
17 repeatedly talking about orders of
18 unusual size, unusual frequency or an
19 unusual pattern, correct?

20 A. That is the section that
21 says you need to have a -- design and
22 operate a system to disclose orders --

23 Q. Or to identify suspicious
24 order monitoring.

1 A. Yes. And to inform the
2 field office. And then suspicious orders
3 include orders of unusual size, orders
4 deviating substantially from a normal
5 pattern, and orders of unusual frequency.

6 Q. And where are you reading
7 that from?

8 A. He puts it on the background
9 information. He reads the entire
10 section, 1301.74.

11 Q. And that's on Page 5?

12 A. Five.

13 Q. Right.

14 A. Yeah, mm-hmm.

15 Q. And that's the same Title

16 21 --

17 A. Yes.

18 Q. -- Code of Federal
19 Regulations, 1301.74(b)?

20 A. Yep.

21 Q. And, "Suspicious orders
22 include orders of unusual size, orders
23 deviating substantially from a normal
24 pattern, or orders of unusual frequency."

1 And the conclusion that DCAG
2 came to in the first draft of the report
3 before it was ever circulated to you and
4 before you provided any comments on it,
5 was that the Janssen system complied with
6 those regulations?

7 MR. JANUSH: Objection.

8 BY MR. BARKER:

9 Q. Correct?

10 A. Yes.

11 Q. Now, in this draft that we
12 are looking at, we got to Page 14 of the
13 document. And there, there was a
14 sentence that was highlighted, not by
15 Mr. Woodworth or you, but by Mr. Janush,
16 correct?

17 A. Yes.

18 Q. And Mr. Janush asked you
19 some questions about that sentence,
20 correct?

21 A. Yes, he did.

22 Q. Okay. Let's go to the
23 e-mail exchange that relates to that
24 sentence. If you can pull out from the

1 stack that you have there Exhibit 27.

2 Do you have Exhibit 27 in
3 front of you?

4 A. Yes.

5 Q. Okay. And so let's go to
6 the second page of Exhibit 27. And we
7 want to go down to the February 5th
8 e-mail from you to Mr. Woodworth, right?

9 A. Mm-hmm.

10 Q. You write, "Hello, Terry.
11 During the review last week, Brian
12 pointed out one statement that I think
13 needs to be clarified. The below
14 statement in red can be misleading.
15 Perhaps you could consider rewording?
16 Something like, 'Due to the current
17 algorithm and order investigation
18 process, there has not been any deemed
19 suspicious" -- I think you mean any
20 orders deemed suspicious -- "that would
21 require reporting."

22 MR. JANUSH: Objection.

23 BY MR. BARKER:

24 Q. Did I read that correctly?

1 A. Yes.

2 Q. Okay. And the sentence that
3 was highlighted is right there. And so
4 although we don't have this document in
5 color, I'll ask you, is that the sentence
6 that was in red?

7 A. Yes.

8 Q. Okay. Did you think that
9 that sentence that we've highlighted here
10 at the bottom, that appeared in the
11 original draft report was misleading?

12 A. Yes.

13 Q. Why?

14 A. Because it did not
15 specifically say whether it was the
16 algorithm or our processes, like our
17 compliance program. It just said our SOM
18 has not reported.

19 Q. Okay. Are you saying that
20 it was incorrectly suggesting that the
21 SOM program wasn't working?

22 A. Right.

23 Q. Did you understand it to be
24 Mr. Woodworth's intent to suggest that

1 the Janssen SOM program wasn't working?

2 A. No.

3 Q. Because he concluded that it
4 was compliant, correct?

5 MR. JANUSH: Objection.

6 THE WITNESS: Yes.

7 BY MR. BARKER:

8 Q. Okay. And then Mr. Janush
9 went over the rest of this e-mail with
10 you earlier. I won't belabor that.

11 But Mr. Woodworth writes
12 back. And he says, "I am happy to delete
13 this sentence altogether. It really
14 doesn't fit with the recommendations
15 being made."

16 Correct?

17 A. Yes.

18 Q. Okay. Did Mr. Woodworth
19 agree with you that it was potentially
20 misleading to phrase the sentence the way
21 that he'd originally phrased it?

22 A. It appears that he agrees.

23 MR. JANUSH: Objection.

24

1 BY MR. BARKER:

2 Q. And it was Mr. Woodworth's
3 idea to remove the sentence as opposed to
4 modify it to address your concern,
5 correct?

6 A. Yes.

7 Q. Can you also pull out
8 Exhibit 24 from that stack that you have
9 there. This was another e-mail that
10 Mr. Janush asked you about. And in
11 particular, he was focusing on this
12 paragraph down at the bottom, where
13 Ms. Chikwendu had sent you a draft e-mail
14 that said, "We currently have a process
15 to flag unusual" -- I guess that should
16 be unusual orders -- "based on List 1
17 chemicals and is not up to current
18 industry practice." Right?

19 A. Right.

20 Q. And it continues, and it
21 says the other things that Mr. Janush
22 went over with you.

23 Now, I recognize that you
24 already said that you disagreed with

1 them. And I also recognize that
2 Mr. Janush pointed out that you could
3 have changed them, and you didn't.

4 Why didn't you change more
5 of this if you didn't agree with it?

6 A. Well, this summary was to
7 relay to the leaders why it was important
8 that we address the algorithm to make
9 sure that the algorithm factors in all of
10 the requirements.

11 Q. And was the funding being
12 sought by Ms. Chikwendu for all
13 enhancements to the entire SOM program,
14 or was this just for part of it?

15 A. This was for the IT effort.

16 Q. The algorithm itself?

17 A. Yes. The IT effort for the
18 algorithm, and we were also asking for
19 funding for the downstream IT effort, for
20 the know your customer.

21 Q. Okay. And so although it
22 doesn't say algorithm here, that was the
23 whole point of what you were seeking
24 funding for, correct?

1 A. Yes.

2 Q. And it was the algorithm
3 that wasn't up to current industry
4 practice, correct?

5 A. Correct.

6 Q. But the overall JOM
7 suspicious order monitoring program was,
8 correct?

9 MR. JANUSH: Objection.

10 THE WITNESS: Yes.

11 BY MR. BARKER:

12 Q. Can you pull out Exhibit 37,
13 38, and 40 that you were previously asked
14 about.

15 A. Yes. I have to find 37.

16 Q. 37 got attached through 47-A
17 through D. Now do you have it?

18 A. Yes, I have it now.

19 Q. So in Exhibit 37, as we've
20 gone over a couple of times before. We
21 have the definition of the algorithm, the
22 operation that is being done by the
23 algorithm, I should say, of three times
24 300 percent of the calculated 12-month

1 per weekly average, correct?

2 A. Yes.

3 Q. But then Mr. Janush showed
4 you two other similar looking documents,
5 Exhibit 38 where there is a shorter
6 version of the definition here at
7 Paragraph 3.1. And I'm marking it on the
8 screen.

9 And he also showed you
10 Exhibit 40, where there's a similar
11 shortened definition.

12 Okay. So the documents with
13 the shortened definition, Exhibits 38 and
14 40, how, if at all, are they different
15 from Exhibit 37?

16 A. 38 and 40 are different
17 versions of a standard operating
18 procedure that goes over the high
19 level -- the order processing
20 investigation of suspicious and excessive
21 orders.

22 Exhibit 37 is the work
23 instruction, which is more like the
24 task-driven execution work that's done

1 when an order is placed.

2 Q. So is the work instruction
3 required to be more precise than the
4 standard operating procedures that we saw
5 in Exhibit 38 and 40?

6 MR. JANUSH: Objection.

7 THE WITNESS: It is more
8 detailed about the tasks that are
9 done -- performed for that
10 process.

11 BY MR. BARKER:

12 Q. Okay. For purposes of the
13 suspicious order monitoring process at
14 Janush, do the definitions provided in
15 the SOPs marked as Exhibit 38 and 40,
16 modify or change in any respect the
17 actual definition of the algorithm that
18 is in Exhibit 37?

19 A. No.

20 MR. JANUSH: Objection.

21 THE WITNESS: No.

22 BY MR. BARKER:

23 Q. So can you also pull out
24 Exhibit 29, which is another version of

1 the DCAG report that was used by
2 Mr. Janush.

3 Okay. And do you recognize
4 Exhibit 29 as the last version of the
5 DCAG report provided by Mr. Woodworth?

6 A. Let me check. Yes.

7 Q. And in the last version that
8 he provided, it still concludes on Page
9 2, correct, that the DCAG evaluation
10 found that the suspicious order
11 monitoring program for the JOM site in
12 Shepherdsville, Kentucky complies with
13 the DEA requirements set forth in the
14 federal regulations, correct?

15 A. Correct.

16 Q. Did Mr. Woodworth ever
17 change that conclusion?

18 A. No.

19 Q. Have you or anyone on your
20 team been in contact with the DEA
21 regarding suspicious order monitoring
22 this year? Actually, you know what,
23 that's a silly question, because I think
24 Mr. Janush actually showed you something.

1 Let's mark that document.

2 Let's do it that way.

3 MS. WINCKEL: The one that
4 we already looked at?

5 MR. BARKER: Yes. It would
6 be -- do we have the exhibit
7 number for that.

8 MS. WINCKEL: Yes, 31.

9 BY MR. BARKER:

10 Q. Can you pull out Exhibit 31
11 from your stack.

12 Okay. So as we established
13 before, this is -- this is a RACR form,
14 correct?

15 A. Yes.

16 Q. And it's one of those forms
17 that's prepared in the ordinary course of
18 business?

19 A. Yes.

20 Q. And this relates to a
21 contact by Stephanie Dixon of -- in your
22 group?

23 A. No, she's not in my group.

24 Q. Oh, she's not in your group.

1 Who is Stephanie Dixon?

2 A. She reports into quality and
3 compliance at JOM.

4 Q. Okay. But this is the
5 report that she prepares over the
6 communication that she has with DEA,
7 correct?

8 A. Correct.

9 Q. And this was with Ben
10 Vinson, who was a supervisor at the
11 Louisville office of the DEA, correct?

12 A. Correct.

13 Q. Okay. And Mr. Janush went
14 over one of the items that she discussed,
15 correct?

16 A. Yes.

17 Q. Okay. And that was the
18 instruction that -- it says -- he -- what
19 he told her was, "Technically reporting
20 should occur when we do not deem
21 suspicious but it has been flagged and we
22 released it for the reason, except for
23 the reasons listed in the questions above
24 that do not need to be reported."

1 Right?

2 A. Yes.

3 MR. JANUSH: Wrong -- when
4 JOM does not deem, not "we."

5 MR. BARKER: I was just
6 reading the statement. But you
7 can substitute the word JOM if you
8 want.

9 MR. JANUSH: Where are you
10 reading from?

11 THE WITNESS: From the
12 contact report.

13 MR. BARKER: From Page 2,
14 right there on the screen. I was
15 highlighting --

16 MR. JANUSH: My apology. I
17 was reading a different provision.

18 THE WITNESS: He was reading
19 the actual e-mail sent to DEA.

20 MR. JANUSH: Right.

21 MR. BARKER: I was reading
22 from the RACR, which is what I
23 said I was doing.

24 MR. JANUSH: I'm sorry.

1 BY MR. BARKER:

2 Q. Okay. Right. And the
3 notion that the -- that an office of the
4 DEA wanted to know about investigated
5 orders and not just those that were
6 deemed suspicious after investigation was
7 a new notion to you, correct?

8 MR. JANUSH: Objection.

9 THE WITNESS: It was a new
10 expectation.

11 BY MR. BARKER:

12 Q. New expectation. Okay. Had
13 you been told something different before?

14 A. We were not told anything
15 about our investigation process.

16 Q. And you'd previously
17 submitted your suspicious order
18 monitoring protocols to the DEA agents
19 from the Louisville office when they came
20 for multiple inspections at the Kentucky
21 distribution center, correct?

22 A. Correct.

23 Q. And those were the ones who
24 knew that they had not received any

1 reports of suspicious orders from Janssen
2 in all the years that they had been
3 there, correct?

4 MR. JANUSH: Objection.

5 THE WITNESS: Correct.

6 BY MR. BARKER:

7 Q. And they never had any
8 observations or criticisms about that
9 practice, correct?

10 A. Correct.

11 Q. Was Mr. Vinson new to the
12 Louisville DEA office?

13 A. Yes.

14 Q. And how do you know that?

15 A. Stephanie records it on the
16 first page.

17 Q. Let's go there. She reports
18 here that Mr. Vinson has over 23 years
19 with DEA starting in Sacramento, El Paso,
20 and now Louisville, correct?

21 A. Correct.

22 Q. So he's the new guy in town,
23 right?

24 A. Correct.

1 Q. Okay. And even though he
2 was changing what information wanted to
3 be provided, you still agreed to provide
4 that information, correct?

5 A. Correct.

6 Q. Let's talk about another
7 regulatory contact that you had in the
8 same time period.

9 MR. BARKER: Let's mark as
10 Exhibit 56 another RACR beginning
11 with JAN-MS-03124076 and running
12 through 4079.

13 (Document marked for
14 identification as Exhibit
15 Janssen-Dempsey-56.)

16 THE WITNESS: This wasn't
17 done by me. Again, this was done
18 by Stephanie.

19 BY MR. BARKER:

20 Q. I understand.

21 A. Okay. You had said that I
22 had. I just wanted to clarify. I did
23 not.

24 Q. Okay. I said you. I meant

1 that in the larger sense, Janssen.

2 A. Okay.

3 Q. I'm happy to be corrected.

4 Janssen had another contact with the DEA
5 on this issue in 20 -- in 2019, correct?

6 A. Correct.

7 Q. Okay. So this is another
8 RACR prepared in the ordinary course of
9 business at or about the time of the
10 events in question by somebody
11 responsible for preparing it, correct?

12 A. Correct.

13 Q. Okay. And, again, the
14 contact is Ms. Dixon at Janssen, correct?

15 A. Correct.

16 Q. And this time the DEA
17 contact is somebody named Roxanna Soraya,
18 correct?

19 A. Yes.

20 Q. And where is she?

21 A. She's Newark DEA.

22 Q. She's in the Newark office,
23 New Jersey. And tell me what -- what
24 this RACR contact is about.

1 A. Well, during the inspection
2 of Franklin distribution center in
3 September of 2018, Stephanie and Roxanna
4 spoke about suspicious order monitoring.

5 Q. Okay.

6 A. And if you go to the back
7 page. You can see the original e-mail
8 that she sent to Roxanna. So she wanted
9 to, "Confirm our conversation during the
10 September 2018 inspection at Franklin
11 distribution center. During the topic of
12 suspicious order monitoring, we discussed
13 that JOM is not required to report a
14 flagged order to the Newark office but is
15 to report orders once the investigation
16 had been completed and the order has been
17 identified as suspicious. Please let me
18 know if this requirement has changed or
19 if I have stated it incorrectly.

20 "Thank you."

21 Q. So this is an e-mail from
22 Stephanie Dixon, right? We're going to
23 go back to the prior page. It's from
24 Ms. Dixon to Roxanna Soraya of the Newark

1 DEA office confirming a conversation that
2 they had, right?

3 A. Yes.

4 Q. Okay. And in this
5 conversation, the exact opposite advice
6 is being provided by the Newark DEA's
7 office as to what they want to see,
8 correct?

9 A. Correct.

10 Q. They only want to see
11 reports of orders that have been deemed
12 suspicious after an investigation and not
13 all orders that are flagged, correct?

14 A. Correct.

15 Q. And is that consistent with
16 the guidance that you had been provided
17 by the Kentucky DEA office up to the
18 communication with Mr. Vinson?

19 MR. JANUSH: Objection.

20 THE WITNESS: Up until then,
21 that was the understanding.

22 BY MR. BARKER:

23 Q. That it had been provided to
24 Janssen, correct?

1 A. JOM, correct.

2 Q. Now, let's go back to
3 Exhibit 31 and the communication between
4 Ms. Dixon and Mr. Vinson at that
5 particular location.

6 Now, she doesn't argue with
7 Mr. Vinson about what he's asking her to
8 provide, correct?

9 A. Correct.

10 Q. She doesn't say, "But I was
11 just told by the New Jersey DEA office
12 that they only want to see orders after
13 they are deemed suspicious following an
14 investigation," correct?

15 A. Correct.

16 Q. Okay. Is it the practice of
17 Janssen to provide whatever information
18 they understand DEA wants to know about
19 potentially suspicious orders?

20 A. Yes. No matter what
21 district, whatever the DEA at that
22 district requires, we would like to make
23 sure we're meeting their expectations in
24 providing the data.

1 Q. Okay. And so you followed
2 the guidance of the local DEA offices in
3 terms of what they want to see in
4 suspicious order monitoring, correct?

5 A. Correct.

6 Q. And in this particular case
7 that we're looking at here in Exhibit 31,
8 you provided the report of all flagged
9 orders, even though none were deemed to
10 be suspicious to DEA Agent Vinson,
11 correct?

12 A. Correct, even though
13 technically he did not want to see the
14 orders that he answered the questions
15 above.

16 Q. Okay. And that was provided
17 by the e-mail we see here on January 21st
18 of 2019, correct?

19 A. Mm-hmm, correct.

20 Q. Have you heard anything from
21 Agent Vinson with him having an issue
22 with any of the orders that were cleared
23 after being flagged as listed on that
24 report?

1 MR. JANUSH: Objection.

2 THE WITNESS: Stephanie has
3 not told me if he has replied with
4 any feedback.

5 BY MR. BARKER:

6 Q. If he had replied with
7 negative feedback, criticizing an order,
8 would Ms. Dixon have told you that?

9 A. Yes, she would.

10 Q. And you would expect that as
11 part of her job, she would have written
12 you a memo or a report that he had
13 contacted her to say that he had an issue
14 with one of the orders that had been
15 released, correct?

16 A. Correct.

17 MR. BARKER: No further
18 questions.

19 MR. JANUSH: Off the record.

20 THE VIDEOGRAPHER: Stand by,
21 please. The time is 5:19 p.m.
22 Off the record.

23 (Short break.)

24 THE VIDEOGRAPHER: We are

1 back on the record. The time is
2 5:49 p.m.

3 - - -

4 EXAMINATION

5 - - -

6 BY MR. JANUSH:

7 Q. Hi, Ms. Dempsey. I'm going
8 to put before you Exhibit 43. It's the
9 Appendix E-3 that your counsel,
10 Mr. Barker, had represented came from a
11 capture from the internet between
12 April 17, '01, and October 18, 2003. And
13 it concerned suspicious order reporting
14 system for use in automated tracking
15 systems.

16 Do you want to pull it up
17 before you, or are you just going to rely
18 on what I have on the screen? Which you
19 can do. I want you to be comfortable.

20 A. It's exhibit number --

21 Q. It's Exhibit 43.

22 A. Okay. Got it.

23 Q. Okay. And with respect to
24 Exhibit 43, Mr. Barker had asked you some

1 questions as to where your three times
2 the order -- average order requirement
3 comes from. And I'm paraphrasing. But
4 is it your testimony today that the
5 genesis of Janssen's or JOM's algorithm
6 to spot suspicious orders comes from this
7 Appendix E-3?

8 MR. BARKER: Object to form.

9 THE WITNESS: The
10 calculation that is used is based
11 on this, yes. It was based on
12 this -- this guidance that was
13 provided.

14 BY MR. JANUSH:

15 Q. Do you know what this
16 actually is?

17 A. Yes.

18 Q. What is it?

19 A. It was the guidance that
20 they provided for suspicious order
21 monitoring for pseudoephedrine and
22 ephedrine products.

23 Q. That's right. It was the
24 guidance that was provided for -- well,

1 let me ask a different question.

2 Do you know how this
3 guidance was to be used in calculating a
4 suspicious order for a List 1 chemical?

5 MR. BARKER: Object to form.

6 THE WITNESS: It is my
7 understanding that List 1 -- the
8 companies that distribute and
9 handle the pseudoephedrine and
10 ephedrine products needed to have
11 a suspicious order monitoring
12 program. And this was guidance
13 provided to them on how to set up
14 thresholds for the customers.

15 BY MR. JANUSH:

16 Q. Okay. You know that this
17 isn't a realtime suspicious order
18 monitoring threshold, right?

19 A. This was guidance that we
20 used as -- this was what was out there
21 from DEA to -- that registrants had
22 available, and they interpreted it, and
23 we used it in our program.

24 MR. JANUSH: Move to strike.

1 Nonresponsive.

2 BY MR. JANUSH:

3 Q. You know this wasn't a
4 realtime suspicious order monitoring
5 threshold; isn't that true?

6 MR. BARKER: Object to form.

7 THE WITNESS: What do you
8 mean by realtime suspicious order
9 monitoring threshold?

10 BY MR. JANUSH:

11 Q. You were --

12 A. This --

13 Q. I'll answer. I'll answer.

14 A. This -- we --

15 Q. You were required by the
16 Code of Federal Regulations to create a
17 suspicious order monitoring program and
18 to not release an order that may be
19 deemed suspicious, correct?

20 MR. BARKER: Object to form.

21 THE WITNESS: The regulation
22 say that you need to have a system
23 that monitors orders.

24 BY MR. JANUSH:

1 Q. And not to release an order
2 that might be suspicious, correct?

3 MR. BARKER: Object to form.

4 THE WITNESS: It says that
5 any orders that are deemed
6 suspicious are not to be released.

7 BY MR. JANUSH:

8 Q. Right. So let's go to what
9 this actually is.

10 Let's read it together.

11 "This formula" -- "This
12 voluntary formula is for use by
13 distributors to wholesale and retail
14 levels. The formula calculates the
15 quantity which, if exceeded in one month,
16 constitutes an order which may be
17 considered excessive or suspicious and
18 therefore require reporting to DEA."

19 Let me stop there.

20 Do you understand the
21 concept that this is a appendix that
22 causes the wholesaler or distributor to
23 look back at all orders from the prior
24 month?

1 MR. BARKER: Object to form.

2 BY MR. JANUSH:

3 Q. Do you understand that?

4 MR. BARKER: Object to form.

5 THE WITNESS: I understand
6 what it reads right here.

7 BY MR. JANUSH:

8 Q. Do you understand what I
9 just asked?

10 A. Yes.

11 Q. Okay. And go to the first
12 paragraph. "Add purchased quantities for
13 the last 12 months for same customers
14 within same distribution center and
15 customer type (hospital, pharmacy, or
16 other) for any List 1 chemical containing
17 items stocked by the distribution
18 center."

19 And it goes on to say, in
20 Paragraph 2, "Add customer months for
21 every record used in above total. Months
22 within the last 12 that customer
23 purchases of the item were not zero."

24 And in 3, "Divide total

1 quantity purchases by the total customer
2 months."

3 And in 4, "Then multiply by
4 the factor below to give the maximum
5 amount that the customer can order per
6 month before showing up on the suspicious
7 order report."

8 Do you see that?

9 A. Yes.

10 Q. This is woefully different
11 than a suspicious order monitoring system
12 for a Schedule II product, correct?

13 MR. BARKER: Object to form.

14 THE WITNESS: This is
15 guidance that was out there as an
16 example of thresholds to set up
17 for, and it even says they are
18 controlled substances containing
19 this one.

20 MR. JANUSH: Move to strike
21 as nonresponsive.

22 BY MR. JANUSH:

23 Q. What I read is woefully
24 different than a suspicious order

1 monitoring system for a Schedule II
2 product; isn't that right?

3 MR. BARKER: Object to form.

4 THE WITNESS: No, because
5 the C.F.R. doesn't specify what
6 your order monitoring system is
7 supposed to have. It says you
8 just have to have a system.

9 BY MR. JANUSH:

10 Q. That's right. But the
11 system has to operate in real time, not a
12 month later, right?

13 A. We took the calculation and
14 we are doing realtime orders being placed
15 based on weekly average for a 12-month
16 period.

17 Q. But this entire Appendix E-3
18 concerns looking back a month later at
19 the month's prior orders.

20 MR. BARKER: Object to form.

21 THE WITNESS: But we are
22 using this for our factor that we
23 are -- when we're monitoring the
24 historical value. We were looking

1 for guidance on what we should be
2 using, and this is the only thing
3 that was available in 2005 or
4 2006, and that told us that we
5 should use a factor three when we
6 are evaluating historical selling
7 patterns for the past 12 months.

8 BY MR. JANUSH:

9 Q. But you made it seem like
10 the DEA told you that this is what you
11 should be using.

12 A. I said this was guidance out
13 there that, as we were developing a
14 program, was available for us to see what
15 DEA may be expecting others to do.

16 Q. DEA never told you, use
17 Appendix E-3 to set your thresholds for
18 your realtime system, did they?

19 A. No. But they never said
20 what we were doing wrong to start with.

21 Q. Okay. Let me ask you a
22 different question. Beyond letting the
23 DEA know that you monitored orders for
24 three times the average weekly order

1 based on the rolling 12-month -- past
2 12-month period, did you ever write to
3 the DEA and advise them, "We don't follow
4 the regulation and track orders of
5 atypical size or orders of -- or address
6 frequency in our algorithm"?

7 MR. BARKER: Object to form.

8 THE WITNESS: There was
9 nothing there that says the
10 algorithm had to take care of
11 those three factors. We had an
12 algorithm that looked at the
13 quantity. It also did give,
14 inadvertently, frequency and
15 pattern, because if a customer
16 didn't order that SKU in
17 12 months, we got a flag.

18 And our overall program took
19 in effect the pattern and the
20 frequency. And we reviewed it
21 with them --

22 BY MR. JANUSH:

23 Q. You keep --

24 A. -- numerous times.

1 Q. You keep going back to that
2 situation where a customer doesn't order
3 a product in 12 months. But there is a
4 converse situation that I showed you
5 today using Cardinal as an example --
6 hold on -- where a customer orders a
7 significant amount of product and breaks
8 it up every three and four and five days.

9 MS. BOODY: Object to form.

10 BY MR. JANUSH:

11 Q. Do you appreciate that?

12 MR. BARKER: Object to form.

13 THE WITNESS: Well, that
14 data you provided doesn't -- I
15 cannot tell you that was a
16 significant quantity because 600
17 bottles in their main hub --

18 BY MR. JANUSH:

19 Q. 600 cases.

20 A. 600 cases that goes to their
21 main hub that gets distributed across the
22 country, and you saw there's 250
23 locations in one area of Florida. So
24 600 cases?

1 Q. But it wasn't just
2 600 cases, was it? It was 600, followed
3 by another 400 or followed by another
4 500. It was -- it was hundreds upon
5 hundreds within days apart.

6 MR. BARKER: Object to form.

7 MS. BOODY: Object to form.

8 THE WITNESS: But we are
9 looking at, on a quarterly basis,
10 the total amount of material
11 they're receiving versus our other
12 J&J products. And it didn't flag
13 that they were saying a
14 significant quantity.

15 As a matter of fact, in that
16 one or two-year period, the trends
17 were going down in that one area
18 in Florida of our Schedule IIs,
19 which was Duragesic and Nucynta.

20 BY MR. JANUSH:

21 Q. But opioid products aren't
22 like your other J&J products, are they?

23 MR. BARKER: Object to form.

24 MS. BOODY: Object to form.

1 BY MR. JANUSH:

2 Q. Opioid products aren't --
3 we're not talking about a standard
4 prescription that's a non-opioid drug,
5 are we?

6 MR. BARKER: Object to form.

7 THE WITNESS: Can you repeat
8 what you're trying to say?
9 Because we are monitoring
10 Duragesic, and we are also
11 monitoring Concerta, which isn't
12 an opiate. We're also monitoring
13 the Nucynta. And I'm trying to
14 understand what you're saying,
15 because the suspicious order
16 monitoring program is a system.
17 It's not just an algorithm.

18 So whether the algorithm is
19 flagging all three or your overall
20 program is encompassing all
21 three --

22 BY MR. JANUSH:

23 Q. But you don't get to the
24 overall program unless the algorithm

1 flags the order to begin with. I'm
2 talking about in real time, as you
3 testified earlier today with me, you
4 don't get to a suspicious order review
5 unless the algorithm flags a particular
6 order initially?

7 A. For the particular order,
8 but we do look at the entire order
9 shipped to that customer.

10 Q. But you do that as like a
11 monthly meeting, right?

12 A. But it's still looking at
13 what where we've distributed to the
14 customer --

15 Q. But it's too --

16 A. -- on a whole.

17 Q. When you've done the monthly
18 meeting, you've already shipped the
19 product, right?

20 A. Yes, but if there was an
21 order that was not typical, there had
22 been an investigation.

23 Q. But again, not typical is
24 viewed against -- not typical is viewed

1 against your initial algorithm, is what
2 flags what's not typical, right?

3 MR. BARKER: Object to form.

4 BY MR. JANUSH:

5 Q. Day one, realtime, shipping
6 an order, it's your algorithm that flags
7 the order, right?

8 MR. BARKER: Object to form.

9 THE WITNESS: Not
10 necessarily, because if we know
11 that there's a change downstream,
12 the customer has gotten a new
13 contract, we know in advance that
14 there's going to be an uptick in
15 demand. And before the order is
16 placed -- for example, when we
17 reviewed with Kentucky DEA,
18 because of the opioid tax, we were
19 asked to ship directly to New
20 York.

21 So we knew that we had no
22 history going to New York. So no,
23 the order system did not flag,
24 because we knew in advance that we

1 were shipping to New York State
2 with no history. And we had to do
3 an investigation to figure out how
4 much typically goes to New York
5 prior to the order.

6 So you are just focused on
7 the algorithm. But I'm saying our
8 overall suspicious order
9 monitoring program, there's other
10 components to it.

11 BY MR. JANUSH:

12 Q. Those other components,
13 though, don't typically come into play in
14 the regular course of business when you
15 have rolling customers who are known to
16 you. We're not talking about the rare
17 issue of the opioid tax, and having a
18 base level of knowledge of zero, and
19 having to investigate on the front end.
20 With a customer that is known to you and
21 has been purchasing from you, your
22 algorithm is the trigger to start an
23 investigation, true or false?

24 MR. BARKER: Object to form.

1 THE WITNESS: For our
2 established products, we place the
3 order. We know when the customer
4 orders because they -- the big
5 three have their days when they
6 place the orders. We know what
7 they historically order. And if
8 there is an increase, the
9 algorithm does tell us if there is
10 an atypical ordering pattern.

11 BY MR. JANUSH:

12 Q. My question was, with a
13 customer that is known to you and has
14 been purchasing from you, your algorithm
15 is the trigger to start an investigation,
16 true or false?

17 MR. BARKER: Object to form.

18 THE WITNESS: And I'm saying
19 in the typical business, yes, an
20 order goes through the algorithm,
21 and it's reviewed. And if it
22 comes up as flagged, we
23 investigate. But there are orders
24 that we know in advance that are

1 not -- that there's going to be a
2 change, that we know in advance
3 and we do the analysis ahead of
4 time.

5 BY MR. JANUSH:

6 Q. Right.

7 A. So it's not just the
8 algorithm.

9 Q. But in the scheme of your
10 orders, that's a relatively small
11 component, isn't it?

12 A. For the products that we
13 have remaining --

14 Q. I'm not talking about
15 remaining. I'm not talking about present
16 day. I'm going back over a history.
17 This case is about many more years than
18 2019.

19 Do you understand that as a
20 concept?

21 A. Yes.

22 Q. Okay. So can you answer my
23 question?

24 A. Can you repeat the question?

1 Q. First I said, in the scheme
2 of your orders, that's a relatively small
3 component, isn't it?

4 A. Today it is.

5 Q. I'm not talking about C-II
6 orders. I'm talking about the -- looking
7 at the rare purchaser who might not have
8 a history with you. That is a rare
9 issue. I mean, I showed you a
10 spreadsheet. I could pull it up from
11 2013 and go through every order of every
12 big three purchase that was in date order
13 with you. There are literally hundreds
14 and hundreds of lines. Those purchases
15 from your big three, which make up over
16 70-something percent of your total order
17 history, those are your regular daily
18 routine orders, true or false?

19 MR. BARKER: Object to form.

20 THE WITNESS: In 2013, yes.

21 BY MR. JANUSH:

22 Q. Okay. How about in 2010?

23 A. 2010, I don't recall the
24 volume would have been that.

1 Q. I'll pull up at a break some
2 of those sales Excel files as well.

3 I'm going to move to
4 Exhibit 44, this big stack of documents.
5 So this was -- this Exhibit 44 was
6 represented to be the validation
7 documentation for the algorithm, wasn't
8 it?

9 A. It is the validation
10 documentation for Change Request 10029
11 which included the algorithm and all of
12 the components that were needed to make
13 the report run.

14 Q. Yes. This is much, much,
15 much, much, much more comprehensive than
16 just addressing the mathematical
17 algorithm, isn't it?

18 A. It is all of the elements
19 that are needed to make the report run.

20 Q. Yes. It's -- this is
21 literally the documentation to create the
22 SAP report system for your ordering
23 system -- for your entire order
24 monitoring system, isn't it?

1 A. This is all of the technical
2 design documents, the test scripts that
3 were done in 2006 to deliver the
4 DEA-related suspicious order reports that
5 are used in these SOPs.

6 Q. Right. It's even more than
7 that though, isn't it? It contains --
8 well, let me ask you something.

9 Do you have personal
10 knowledge of these documents to have
11 answered Mr. Barker's question as to
12 whether this -- this document, as a
13 single document represented the
14 validation documentation for the
15 algorithm?

16 MR. BARKER: Object to form.

17 THE WITNESS: I have had
18 experience with SAP projects in
19 the past. As a matter of fact I
20 was in IT at the time, 2006. So I
21 knew this project was underway
22 because it was happening when my
23 project was going.

24 So I asked IT to please

1 provide all of the validation
2 documentation that was required to
3 test the configuration for this
4 DEA project that JOM has
5 requested.

6 BY MR. JANUSH:

7 Q. Okay. When you say I was in
8 IT at the time, what does that mean?

9 A. Well, in -- from 2006, in
10 March of 2006 I was the SAP COE IT person
11 for Noramco. And we had just --

12 Q. What does that mean?

13 A. SAP is the IT system. And I
14 was responsible for the project that put
15 Noramco on the same SAP. So as -- in my
16 role I was familiar with the validation
17 practices and processes that were
18 required to make changes in SAP.

19 Q. Okay. So are you familiar
20 enough, then, to have thumbed through
21 this document and realized this is far
22 beyond just the algorithm validation?

23 A. This contains all of the
24 test script documentation to test the

1 front-end queries for the DEA -- this is
2 everything that was required for the DEA
3 project, which was all of -- the BW
4 report as well as --

5 Q. And what is a BW report?

6 A. Business warehouse.

7 Q. Talk about that. What's
8 that?

9 A. It is a module in SAP where
10 it's separate from the active production
11 for SAP.

12 SAP has a transactional
13 module where the actual movements, the
14 goods issues, the receipts are happening.
15 And then you have this business warehouse
16 where data from the transaction all gets
17 move over, and they use this business
18 warehouse to develop reports so that you
19 can analyze what actually happened on the
20 transactional level.

21 Q. That's totally a different
22 IT concept than the mathematical
23 algorithm to spot a suspicious order,
24 isn't it?

1 A. No, because the
2 transactional data, the actual orders
3 that go into SAP, that's in the
4 production environment. So that's
5 customer service going in, entering in,
6 getting the 222, entering it in. And
7 then the information of everything that
8 was entered every day goes into this
9 business warehouse. And that's where
10 they collect it and they do your
11 algorithm onto the order.

12 Q. Right. But the -- this
13 documentation that is here far exceeds --
14 this is -- how many pages is this? It
15 starts at --

16 A. The thing is you have to do
17 the functional requirements. Then you
18 have to develop specifications. And then
19 every specification requires a test
20 script. And it has to be tested, and the
21 actual results.

22 So, you know, here you go.
23 This is just one way of testing the
24 monthly order quantity average, to make

1 sure it's calculating the average right.

2 I mean, and then this is
3 developing what it looks like, the
4 report, if you ever saw the BW report
5 that flags an order. So what's the
6 screen look like. That's the test.

7 Q. What's a BEX monthly DEA
8 double exception report?

9 A. That was one of the reports
10 referenced in the SOPs, that's run --
11 that they can check to see what's been
12 shipped to the customer over a certain
13 amount of time.

14 Q. And what is the master data
15 list?

16 A. As I mentioned before, it's
17 setting up all of the -- all the
18 customers, what products they're allowed
19 to receive and, you know, the information
20 about the customers, so that this report
21 runs on the right customer order.

22 Q. And let's see. I want to
23 try to get to something different here.
24 I'm trying to skip forward a number of

1 hundreds of pages to...

2 So to be clear, this isn't
3 the issue of what I called fourth grade
4 math in terms of checking an order
5 against all prior orders over the same
6 12 months SKU to SKU.

7 This is the setup of the
8 computer program programming in every
9 order, making sure every order is able to
10 be tracked, isn't it?

11 A. This is for every order, and
12 recognize that -- I don't want to make it
13 more complicated. There are several
14 different types of orders that can be
15 received by a customer. You know, and so
16 SAP had to check. It's not just a
17 simple -- every order has a code number.
18 And so we had to make sure that SAP
19 looked at every single potential code,
20 because some of these wholesalers might
21 want it shipped somewhere else, or it may
22 be going to -- we have different codes
23 for the various shipping logic. So we
24 had to make sure that every potential

1 scenario was identified so we're not just
2 looking at one order type.

3 You know, I know I'm making
4 this really complicated. But there are
5 so many different, like, customer return
6 is an order type. So we wanted to
7 factor -- they just -- different
8 movements out of SAP is an order type.
9 But it's considered a shipment. So we
10 had to make sure that the BW report was
11 looking at that for every customer, every
12 SKU, every type of movement.

13 And that's why there's a lot
14 here. If it was a simple -- I just went
15 in, said so much for this customer, it
16 would have been easier. But there's --
17 it's complex.

18 Q. But I could take your Excel
19 file -- I could take that Excel file that
20 I pulled up earlier today, that came from
21 your company, and I can filter that Excel
22 file for the last 12 months. I can
23 look -- filter it for just the drug type,
24 just the SKU, just the exact milligrams

1 that have been shipped. And I can figure
2 out, divided by 52 weeks, what the
3 average weekly order is, and from that I
4 can compare it to a current order that's
5 placed tomorrow?

6 A. But then you have a data
7 integrity issue and FDA would not be
8 happy.

9 Q. What do you mean I have a
10 data integrity issue?

11 A. Because you can manipulate
12 that Excel sheet to say whatever you'd
13 like it to say and say it was always
14 under the threshold.

15 Q. And how is that, that I
16 would manipulate an Excel spreadsheet by
17 just doing simple math?

18 A. I'm just saying that, you
19 know, if -- using Excel, you're relying
20 on a manual person, a human person to do
21 all these calculations, and they can be
22 prone to make mistakes, which is why we
23 moved to this system, where all the
24 actual shipments are maintained and the

1 history is in here, and it can do the
2 math for you.

3 Q. Got it. So -- so this is --
4 this system, this documentation, is far
5 more than validating just the math, isn't
6 it?

7 A. It's validating all the data
8 that goes into the equation as well as
9 the math.

10 Q. Got it. Got it. It seemed
11 like Mr. Barker and you were representing
12 that this by itself, this whole stack of
13 documents, was just the algorithm
14 validation. And I was seeking to
15 disagree with that. And I think that
16 you've come around to me.

17 A. No, I haven't --

18 MR. BARKER: Object to form.

19 THE WITNESS: -- because
20 this is everything that was needed
21 to make sure that the calculation
22 worked as it was intended and gave
23 us accurate information.
24

1 BY MR. JANUSH:

2 Q. That's a different issue
3 than whether the math ultimately is
4 fourth grade math?

5 MR. BARKER: Object to form.

6 THE WITNESS: If the math
7 equation is not using the right
8 data, it doesn't work, and if it's
9 not validated and working as it's
10 intended.

11 BY MR. JANUSH:

12 Q. Okay. Earlier do you recall
13 that you were shown Exhibit 10 that I
14 marked at Day 1 of your deposition.

15 A. Yes.

16 Q. And you were asked why you
17 continued to ship to Walgreens
18 Perrysburg, Ohio, that was facing an
19 imminent suspicious. And the answer was
20 what?

21 A. They still had an active
22 license.

23 Q. But you knew as compared
24 with the Cardinal situation that your

1 counsel, Mr. Barker, showed you to
2 justify continued shipments to Walgreens'
3 Perrysburg, Ohio distribution center, you
4 knew that this distribution center, the
5 Walgreens center, was about to have their
6 registration pulled, didn't you?

7 A. Right. But we don't ship to
8 Walgreens. We ship to Cardinal that
9 ships to this location. We were
10 monitoring it, so should they lose their
11 license, we would have followed up with
12 the wholesaler.

13 Q. And you answered your
14 counsel by saying something to the effect
15 of the license wasn't pulled, it was
16 still active. It was like the guidance
17 we got from the DEA in the Cardinal
18 situation.

19 Do you remember that?

20 A. Yes.

21 Q. Okay. But the Cardinal
22 situation was different, wasn't it?

23 MR. BARKER: Object to form.

24

1 BY MR. JANUSH:

2 Q. I'm going to pull up
3 Exhibit 45.

4 The Cardinal situation was a
5 specific and narrow inquiry by Brian
6 Strehlke addressing the fact that Janssen
7 was seeing upticks in demands from other
8 Cardinal distribution centers as their
9 system attempts to accommodate customers
10 who cannot presently be supplied by the
11 distribution centers, which have been
12 placed on hold.

13 Do you see that language in
14 the middle of the page of the -- Page 1
15 of the e-mail? It's actually the second
16 page.

17 A. Yes.

18 Q. Do you see that?

19 A. Yeah.

20 Q. Yeah. And so the question
21 was, "Does DEA have any objection to our
22 filling the increased orders to Cardinal
23 distribution centers which have
24 registrations which are still in good

1 standing?"

2 Do you see that?

3 A. Yes.

4 Q. Those were Cardinal
5 distribution centers that were then not
6 currently under investigation.

7 Do you understand that?

8 MR. BARKER: Object to form.

9 THE WITNESS: They had their
10 licenses.

11 BY MR. JANUSH:

12 Q. They were not under
13 investigation.

14 Do you understand that?

15 A. But Cardinal as a whole.

16 Q. No, Cardinal as a whole was
17 not under investigation. Cardinal had
18 specific distribution centers that were
19 placed on hold.

20 Do you understand that
21 distinction?

22 MR. BARKER: Object to form.

23 THE WITNESS: I understand
24 what you're saying.

1 BY MR. JANUSH:

2 Q. And Janssen, Brian Strehlke
3 was asking, does the DEA have an
4 objection to us, Janssen, filling orders
5 to Cardinal distribution centers that
6 aren't on hold?

7 Do you get that?

8 A. Yep.

9 Q. Okay. That's different than
10 the inquiry of whether shipments should
11 be going to a distribution center for
12 Walgreens that's being hotly investigated
13 and about to be shut down by the DEA,
14 isn't it?

15 MR. BARKER: Object to form.

16 BY MR. JANUSH:

17 Q. They're not analogous
18 situations, are they?

19 A. Well, Walgreens, of course,
20 is not our customer. But we were
21 monitoring it.

22 Q. They are not analogous
23 situations, are they?

24 MR. BARKER: Object to form.

1 THE WITNESS: In this case,
2 they are in a similar way that
3 they still had their license.

4 BY MR. JANUSH:

5 Q. Okay. So because -- so you
6 compared --

7 A. And I --

8 Q. -- Cardinal distribution --
9 you know, at this deposition, just
10 moments ago, you compared Cardinal
11 distribution centers that were not under
12 investigation to a Walgreens distribution
13 center that was under a heated DEA
14 investigation that you knew was about to
15 have their license pulled. You equated
16 that, didn't you?

17 MR. BARKER: Object to form.

18 THE WITNESS: We don't
19 know --

20 MR. BARKER: Are you
21 representing that license got
22 pulled, Counsel?

23 MR. JANUSH: I'm
24 representing what I'm

1 representing. I'm asking my
2 question.

3 THE WITNESS: We were
4 watching it, but they had not had
5 their license pulled.

6 BY MR. JANUSH:

7 Q. So you're not willing to
8 address whether the situations were the
9 same or different, are you?

10 MR. BARKER: Object to form.

11 THE WITNESS: It's in
12 regards to being -- having a DEA
13 license --

14 BY MR. JANUSH:

15 Q. I'm not asking whether the
16 DEA license existed. Can you appreciate
17 the situations were different?

18 MR. BARKER: Object to form.

19 THE WITNESS: I can see
20 where you would think that they
21 would be different. But we were
22 still supplying the wholesaler,
23 who was supplying that. And they
24 had not lost their license.

1 BY MR. JANUSH:

2 Q. Moving on to Exhibit 46.

3 Counsel asked you about this DEA site
4 inspection of October 22nd, 2008, of your
5 Franklin distribution center in New
6 Jersey.

7 Do you remember that?

8 A. Yes, I do.

9 Q. Okay. And let's go over
10 summary of Day 1 of the inspection.

11 "Numerous documents were requested and
12 reviewed by the investigators including:
13 JOM Inc., articles of incorporation, list
14 of corporate officers, power of attorney
15 documentation, list of authorized vault
16 personnel -- cage and vault personnel,
17 list of domestic customers, third quarter
18 2008 ARCOS report, returned goods log,
19 DEA 222 forms for receipts and shipments
20 for March 2008."

21 Do you see that?

22 A. Yes, I do.

23 Q. Okay. And then it says,

24 "Investigators also requested a list of

1 all products on hand, current inventory
2 under our distributor registration. They
3 selected four SKUs to audit, along with
4 an audit time frame of close of business
5 12/31/07 through today, 10/22/08."

6 Do you see that?

7 A. Yes.

8 Q. And then it goes on to say,
9 "The investigators" -- on the second
10 page -- "then proceeded to conduct an
11 inventory reconciliation."

12 Nothing about Day 1
13 concerned suspicious order monitoring; is
14 that right?

15 A. No. It reviewed our orders,
16 what was shipped out of the DC.

17 Q. Nothing reviewed suspicious
18 order monitoring; is that right?

19 A. At that time, no.

20 Q. At that time, no, that is
21 not right? Or at that time, you are
22 right?

23 A. At this time you are right,
24 they did not discuss specific on

1 suspicious order monitoring.

2 Q. Okay. And, "Preparation for
3 Day 2. Investigators are expected to
4 complete the inventory reconciliation,
5 review handling of suspicious orders, and
6 conduct a security review," right?

7 A. Yes.

8 Q. But you have no firsthand
9 personal knowledge as you sit here today
10 that that Day 2 happened, do you?

11 A. I was not involved in this
12 inspection, but I know individuals that
13 were that said it did happen. So...

14 Q. You have no personal
15 firsthand knowledge that a Day 2
16 inspection occurred, and you have no
17 record of it at this deposition; is that
18 right?

19 A. I don't have a record of it.

20 Q. Okay. And you're the head
21 of compliance today, not in 2008. I
22 appreciate that.

23 But, I assume you searched
24 for this record of Day 2, right?

1 A. I did make the request, did
2 anybody have it.

3 Q. And nobody could locate it?

4 A. No. It's beyond the seven
5 years records retention.

6 Q. So is the 2008 e-mail that
7 I'm looking at right now, but you found
8 that, right?

9 A. Yep. But somebody kept
10 this. Somebody kept this.

11 Q. Okay. Mr. Barker introduced
12 Exhibit 48 as well. I'll have you pull
13 that up.

14 Exhibit 48 was a notice
15 of -- was titled in the subject of the
16 e-mail. It's dated 7/30/2013. The
17 subject is "Notice of inspection at KDC,
18 29 July, 2013."

19 And in paren, it says "30
20 July 2013 update."

21 Do you see that?

22 A. Yes.

23 Q. It addresses, "Here's the
24 final inspection summary," at the outset.

1 And if you go down a few
2 bullets, it says, "Reason for inspection
3 type: Routine regulatory inspection.

4 "Observations: None.

5 "Primary areas reviewed
6 today."

7 "Security" is the first
8 bullet. "Alarm testing, review of select
9 222 forms, receiving and shipping
10 documents for audit period, 31 of
11 December 2011 to 29 July 2013."

12 In parentheses it says,
13 "January 2012, June 2012, and
14 January 2013."

15 Do you see that?

16 A. Yes, I do.

17 Q. And the second bullet says,
18 "Closing comments indicated primary focus
19 was security and records review.

20 "Primary focus was security
21 and records review. No issues noted
22 during records audit review. Alarm
23 testing results were good. No C.F.R.
24 violations were identified. No report

1 will be issued. The DEA inspection is
2 closed."

3 Do you see that?

4 A. Yes, I do.

5 Q. Suspicious order monitoring
6 was not a primary subject of this
7 inspection, was it?

8 MR. BARKER: Object to form.

9 THE WITNESS: It was part of
10 the inspection, and that closing
11 summary, that's the closing
12 comments that Billy Lane presented
13 in the document attached, exactly
14 what he said, Billy Lane.

15 "Primary focus was security and
16 records review. Audit came out
17 fine for the time frame," that we
18 just -- so she wrote exactly what
19 Billy Lane spoke to.

20 BY MR. JANUSH:

21 Q. What I'm addressing is that
22 the primary areas reviewed were security,
23 alarm testing, and not suspicious order
24 monitoring; isn't that right?

1 MR. BARKER: Object to form.

2 THE WITNESS: She gave a
3 high level summary, and then she
4 sent the attached notes.

5 BY MR. JANUSH:

6 Q. And then when you get to the
7 next -- and that was the Day 2, that was
8 the July 30th day, right? There was a
9 Day 1 as well, correct?

10 A. Yes.

11 Q. If you flip the page, you
12 get to Day 1.

13 A. Yep.

14 Q. And Day 1 also had a primary
15 areas reviewed today, didn't it?

16 A. Yep.

17 Q. Show the jury in this case
18 within this box that I've just
19 highlighted where suspicious order
20 monitoring was a primary area of focus by
21 the DEA.

22 MR. BARKER: Object to form.

23 THE WITNESS: It was
24 embedded in their review, and you

1 can see the daily summary. She
2 says, "See internal notes."

3 BY MR. JANUSH:

4 Q. Not what I asked.

5 MR. BARKER: Actually it is
6 what you asked.

7 BY MR. JANUSH:

8 Q. Show within the box that
9 I've highlighted --

10 A. On the document, okay.

11 Q. -- on the document.

12 A. So they said, "Supply a
13 customer list." So how did you know that
14 the customer list didn't include
15 suspicious order monitoring discussion?

16 Q. Well, suspicious order
17 monitoring is a very specific concept,
18 isn't it?

19 A. And it's a typical topic of
20 discussion, as we demonstrated. They
21 always asked for our SOP when they come
22 to visit.

23 MR. JANUSH: Not my
24 question. Move to strike

1 nonresponsive.

2 BY MR. JANUSH:

3 Q. I was addressing the primary
4 areas reviewed today as catalogued or
5 documented by your own employees. And I
6 asked you to find me where in the primary
7 areas reviewed, suspicious order
8 monitoring was a topic?

9 MR. BARKER: Object to form.

10 THE WITNESS: She did not
11 record it there. She recorded it
12 on the internal notes and the
13 regulatory inspection document and
14 provided it.

15 BY MR. JANUSH:

16 Q. I guess what I'm getting at
17 is, the DEA came for a primary mission
18 that stated for each day, Day 1 and Day
19 2, in the body of these e-mails; isn't
20 that right?

21 MR. BARKER: Object to form.

22 THE WITNESS: Yes.

23 BY MR. JANUSH:

24 Q. And in the context of coming

1 to visit with those primary objectives, a
2 whole host of paperwork was provided that
3 goes beyond -- purportedly provided, as
4 these notes confirm, that was beyond the
5 primary purposes -- went beyond the
6 primary purposes of the inspection, fair?

7 MR. BARKER: Object to form.

8 THE WITNESS: No, because
9 what you don't have is an e-mail
10 from a few months prior to this
11 inspection where DEA reached out
12 to us and said during their
13 inspection this year they're going
14 to review suspicious order
15 monitoring.

16 So that is why we were
17 prepared and had all this
18 information for them.

19 BY MR. JANUSH:

20 Q. Did your counsel introduce
21 that e-mail as well into evidence today?

22 A. No. But he did ask if I was
23 present. And that was the reason why
24 we -- all of us were present, because

1 they wanted -- they asked to talk about
2 suspicious order monitoring.

3 Q. Okay. Suspicious order
4 monitoring is a pretty important topic,
5 and it was really important in 2013,
6 wasn't it?

7 MR. BARKER: Object to form.

8 THE WITNESS: It was a topic
9 that DEA in Kentucky wanted to
10 review with us.

11 BY MR. JANUSH:

12 Q. 2013 is -- was a very
13 significant year in terms of the opioid
14 crisis, wasn't it?

15 A. I don't know.

16 Q. Okay. What I'm getting at
17 is, suspicious order monitoring as a
18 topic is important, and yet it's nowhere
19 listed within the primary areas of review
20 for Day 1 or Day 2, is it?

21 MR. BARKER: Object to form.

22 THE WITNESS: It was part of
23 the discussion and included in the
24 list of documents that we gave

1 them.

2 BY MR. JANUSH:

3 Q. I understand. I understand
4 what you want to answer.

5 A. I was there.

6 Q. I understand.

7 A. I know that it was talked
8 about.

9 MR. JANUSH: Move to strike.
10 Nonresponsive.

11 THE WITNESS: She chose not
12 to write it in a summary because
13 she had it all outlined in detail
14 attached.

15 BY MR. JANUSH:

16 Q. Okay. What does it mean to
17 say that the Kentucky distribution center
18 doesn't import or export scheduled
19 product?

20 A. You get a license based on
21 your activity. And if you had a
22 Schedule -- it would be Schedule III
23 through V, and you want to bring it --
24 it's manufactured in another country, you

1 need to have an import registration, an
2 import license, in order to get the
3 approval and the permits or the
4 declarations to bring it into the
5 country.

6 Q. And so KDC -- I saw a note
7 here. I'm just trying to understand it.
8 I saw a note here that said the DEA
9 investigation at Exhibit 49 was reduced
10 from three days to two days because KDC
11 doesn't import or export scheduled
12 product.

13 A. Right. At this time we were
14 not currently importing any scheduled
15 product, so there was no documentation
16 for DEA to review. And that's why they
17 cut back the inspection time so they
18 could focus on the distributor, which was
19 an active license.

20 Q. You were asked a bunch of
21 questions about this inspection, the
22 DEA's inspection in Kentucky in
23 January 2014. Do you remember that?

24 A. It was --

1 MR. BARKER: Object to form.

2 THE WITNESS: -- January of
3 2015.

4 BY MR. JANUSH:

5 Q. Sorry. January of 2015.

6 It's a --

7 A. Typo.

8 Q. -- typo, right. We figured
9 that out earlier.

10 Do you remember being asked
11 a bunch of questions?

12 A. Yes, I do.

13 Q. And is it the case -- I'm
14 looking at the products. I see that it
15 says for imported materials, the
16 inventory that was noted was tramadol and
17 Ultram.

18 I don't see anything
19 concerning -- oh, I do on this page. I
20 apologize. I see it on the next page on,
21 or two pages later, on January 27th, Day
22 1, 2015, the cage and vault confirmation.

23 So you were asked questions
24 that were directed to you, personally,

1 concerning what was handed over, what was
2 done with respect to this investigation.

3 Were you physically present
4 at this investigation?

5 A. No.

6 Q. Did you hand over any
7 materials at this investigation?

8 A. No.

9 Q. Do you have any personal
10 knowledge as to anything that was done in
11 this investigation other than to what you
12 were told or what you read?

13 A. I had DEA compliance manager
14 Mike Levitt who was the key contact and
15 part of the inspection. He reported in
16 to me.

17 Q. Right. But you -- any
18 testimony concerning you, or the word
19 "you," cannot be read to mean Michele
20 Dempsey; is that right?

21 A. It was JOM.

22 Q. Okay. Did you have
23 differing local procedures versus
24 national procedures for suspicious order

1 for JOM?

2 A. We had -- we had two
3 distribution centers and they used the
4 same SOPs.

5 Q. Okay. In other words, was
6 JOM's -- Johnson Ortho-McNeil standard
7 operating procedures for suspicious order
8 monitoring the same as a national
9 program?

10 A. I don't understand what you
11 mean national program.

12 Q. In other words -- in other
13 words, you had two different distribution
14 centers, right?

15 A. Under the same leadership
16 and quality functions, yes.

17 Q. Right. You didn't have two
18 different standard operating procedures
19 for -- you wouldn't have had two
20 different standard operating procedures,
21 would you have, for suspicious order
22 monitoring? Or would you?

23 A. No, because the suspicious
24 order monitoring procedures that we've

1 reviewed, either they're with DEA
2 compliance or they're with customer
3 service. Each individual distribution
4 center, the material handler, how they
5 ship and pack, because of the different
6 configurations, there may be different
7 SOPs locally -- locally for the material
8 handlers, because it's a different
9 layout, different vaults, different
10 setups in how to do the pick, pack, and
11 ship to the customers.

12 So at a local level there
13 may be some work instructions, job aids
14 that are different based on the
15 activities. But when it comes to
16 suspicious order monitoring, it was the
17 same quality group across both locations
18 that are following the same SOPs all
19 under the JOM.

20 Q. Earlier -- the audit at
21 page -- at Exhibit 26 is the original
22 draft audit from Terrance Woodworth, was
23 presented to you by your counsel.

24 Do you remember that?

1 A. Yes.

2 Q. And your counsel asked you,
3 were any of the improvements that were
4 being discussed at this meeting or in
5 Mr. Woodworth's report, and I think he's
6 referring to the original December 13,
7 2017, meeting -- I'll start again.

8 Were any of the improvements
9 that were being discussed at this meeting
10 or in Mr. Woodworth's report from the
11 Drug and Chemical Advisory Group about
12 improving the suspicious order monitoring
13 system so that you would catch orders
14 that were potentially suspicious that
15 were possibly being missed.

16 Do you remember that?

17 A. I remember that.

18 Q. You answered no, right?

19 A. Right.

20 Q. That doesn't make sense,
21 does it?

22 MR. BARKER: Object to form.

23 THE WITNESS: Yes. We did
24 not design our program -- so let

1 me -- can you repeat what you
2 said? That --

3 BY MR. JANUSH:

4 Q. Wasn't Mr. Woodworth trying
5 to improve your suspicious order
6 monitoring program so that it would catch
7 orders that potentially were being missed
8 under the single-criteria algorithm?

9 A. No.

10 Q. So if I depose Mr. Woodworth
11 in, say, two months from now, do you
12 expect him to testify that he was not
13 seeking to develop a more DEA-compliant
14 suspicious order monitoring algorithm
15 that might take into account other
16 variables and pick up suspicious orders
17 that were being missed by your
18 one-criteria algorithm?

19 MR. BARKER: Object to form.

20 THE WITNESS: Our overall
21 suspicious order monitoring
22 program is compliant.

23 BY MR. JANUSH:

24 Q. That's not what I asked.

1 A. And his recommendations were
2 enhancements to make us ready for any
3 future inspections or expectations that
4 come out of the SUPPORT Act or what --
5 all the new regulations that are going to
6 be coming out of FD -- DEA.

7 MR. JANUSH: Move to strike
8 as entirely nonresponsive.

9 BY MR. JANUSH:

10 Q. You know that I didn't ask
11 that question that you gave that answer
12 to, right?

13 A. He did not --

14 MR. BARKER: It is
15 absolutely responsive.

16 BY MR. JANUSH:

17 Q. So let's --

18 A. He did not come in to give
19 recommendations to make our algorithm
20 find orders that were missing.

21 Q. Okay. Why then did he
22 recommend that you take past order
23 examples and evaluate their
24 circumstances, order patterns, and

1 activity against revised algorithms to
2 determine discrepancies or adjustments
3 needed?

4 A. He wanted us to make sure
5 the thresholds that we set up with -- let
6 me find it.

7 So what he was saying is,
8 once you determined -- using your --
9 well, once you use your historical
10 ordering patterns and frequency and
11 quantities, and you do the statistics to
12 develop your thresholds, take all your
13 past orders through, and evaluate whether
14 you wouldn't see -- basically based on --
15 once you identify the three criteria,
16 that you wouldn't be getting the
17 excessive orders that we're getting right
18 now based on the SKU. And that's
19 basically what he was saying there.

20 Q. So it's your testimony today
21 that Terrance Woodworth and the Drug and
22 Chemical Advisory Group was solely
23 concerned with why Janssen was getting
24 red flags or suspicious orders based on

1 their single-criteria SKU-to-SKU program?

2 MR. BARKER: Object to form.

3 THE WITNESS: No. He was

4 here to review our program, audit

5 it, and provide recommendations so

6 that we could be proactively ready

7 for when new regulations come out

8 from DEA or new expectations are

9 coming out.

10 BY MR. JANUSH:

11 Q. And let's look at again what

12 his recommendations were, because his

13 actual -- what your counsel referred to

14 as conclusions was nothing more than an

15 executive summary. It wasn't

16 conclusions. It was an executive

17 summary, wasn't it?

18 MR. BARKER: Object to form.

19 BY MR. JANUSH:

20 Q. Look at the first page. It

21 was an executive summary; is that right?

22 A. Yes.

23 Q. And then the actual

24 conclusions come at a spot in the report

1 called "Recommendations"?

2 A. It doesn't say conclusion.
3 That's recommendation.

4 Q. It's a heck of a lot
5 stronger than executive summary?

6 THE WITNESS: It doesn't say
7 conclusion.

8 MR. BARKER: Object to form.

9 THE WITNESS: It says
10 recommendations.

11 BY MR. JANUSH:

12 Q. I honestly can't believe
13 you're fighting with me over that word.

14 A. It is --

15 MR. BARKER: I can't believe
16 that you're arguing with the
17 witness over something that
18 doesn't say conclusions. It says
19 recommendations.

20 MR. JANUSH: Right.
21 Recommendations.

22 MR. BARKER: Future actions,
23 not past.

24 MR. JANUSH: Excuse me.

1 Excuse me.

2 MR. BARKER: Well, you're
3 arguing with the witness. So I'm
4 arguing with you.

5 MR. JANUSH: So move to
6 strike counsel's interruptions.

7 BY MR. JANUSH:

8 Q. I'm talking to you. You're
9 my witness. I'm going to ask you some
10 questions about recommendations.

11 You hired an auditor to make
12 recommendations to improve your system,
13 right?

14 A. We hired an auditor to give
15 us recommendations to enhance our current
16 program so that we could be proactive.

17 Q. That's a long way of saying
18 right, isn't it?

19 A. These aren't improvements.
20 These are recommendations. He said we're
21 compliant. These are recommendations to
22 make it better, enhancements.

23 MR. JANUSH: Move to strike.

24 Nonresponsive.

1 MR. BARKER: Object to the
2 objection. It's --

3 MR. JANUSH: Enough.

4 MR. BARKER: -- commentary.

5 BY MR. JANUSH:

6 Q. Let's go to Page 10. At
7 Recommendation 4, he told you to start
8 modifying the existing suspicious order
9 monitoring algorithm and/or adding
10 algorithms to include additional
11 evaluation criteria for each specific DEA
12 basic class of controlled substance
13 handled by J&J; example, fentanyl,
14 methylphenidate, tramadol. Right?

15 MR. BARKER: Object to form.

16 THE WITNESS: Right.

17 BY MR. JANUSH:

18 Q. He told you to consider a
19 base unit of measurement, such as grams
20 of active ingredient, for the SOM
21 algorithms, right?

22 A. Yes.

23 Q. Are you following that
24 instruction going forward, by the way?

1 A. As a matter of fact, today
2 we are receiving thresholds from The
3 Analysis Group on a new product that will
4 be grams for our esketamine product.

5 Q. And a gram-based unit of
6 measurement for a suspicious order
7 monitoring program is more rigorous than
8 the program you've had in place for the
9 last many years, isn't it?

10 MR. BARKER: Object to form.

11 THE WITNESS: I can't answer
12 that question because, in talking
13 to Analysis Group, we are going to
14 be most likely -- we won't be
15 getting the orders that we
16 received that the -- the false
17 positives. So I cannot say
18 whether going to this is going to
19 give us fewer or more orders,
20 because we are launching a new
21 product, so we're going to be
22 receiving a higher number of
23 orders. So I can't give you an
24 answer right now if this is going

1 to be less or more.

2 BY MR. JANUSH:

3 Q. I didn't say less or more.

4 I said more rigorous. And I'm talking
5 about spotting actual suspicious orders.

6 A. That is the intent of going
7 to this, the intent.

8 Q. Right. We're not talking
9 about -- I'm not here to talk about false
10 positives. This case, this opioid
11 epidemic, isn't about false positives.
12 It's about real orders that made it out
13 there that shouldn't have made it out
14 there.

15 Do you understand that?

16 MR. BARKER: Object to form.

17 THE WITNESS: I understand
18 you.

19 BY MR. JANUSH:

20 Q. Okay. Now, I understand
21 that you want to talk about false
22 positives. I want to talk about what
23 Terrance was seeking to do in this audit
24 and in this recommendations. Okay?

1 A. Okay.

2 Q. Next, he said, "Consider
3 separating J&J customers into two or more
4 groups and perform different analyses of
5 orders for these different groups;
6 largest three wholesalers in one group,
7 smaller wholesalers in another group."

8 Do you see that?

9 A. Yes.

10 Q. Are you following something
11 like that going forward in your new
12 program?

13 A. Yes, we are.

14 Q. When he said, "Consider
15 evaluating customer orders for specific
16 DEA basic classes of substances against
17 similar size and geographically placed
18 customers and perform national, regional,
19 state, and perhaps three digit zip code
20 comparisons among like-size customers."

21 Did I read that right?

22 A. Yes, you did read it.

23 Q. Are you implementing any of
24 that in your new protocols?

1 A. You saw the IntegriChain
2 statement of work, so yes, we are going
3 to be going to that level.

4 Q. Okay. And now, at 4-A,
5 Terrance advised, "Stop using this
6 current single-criterion algorithm which
7 selects and holds orders from customers
8 when the quantity of an order is greater
9 than three times, 300 percent, the
10 customer's average weekly order based on
11 a rolling 12-month ordering history from
12 that customer."

13 Did I read that right?

14 A. Yes.

15 Q. And he said, "This algorithm
16 only measures quantity and does not
17 consider frequency or a pattern of
18 ordering by the same customer."

19 Did I read that right?

20 A. Yes, you did.

21 Q. That statement isn't about
22 limiting Janssen's or JOM's false
23 positives. That statement is about
24 improving your program so that you

1 measure the other two C.F.R.-required
2 elements, isn't it?

3 MR. BARKER: Object to form.

4 THE WITNESS: In our
5 algorithm, he is suggesting that
6 we capture all three.

7 BY MR. JANUSH:

8 Q. My question was, that
9 statement isn't about limiting Janssen's
10 or JOM's false positives. That statement
11 is about improving your program so you
12 measure the other two C.F.R.-required
13 elements, isn't it?

14 MR. BARKER: Object to form.

15 THE WITNESS: He is
16 suggesting that we make
17 enhancements to the algorithm to
18 capture more formally the
19 frequency and pattern requirements
20 that we are doing outside --

21 BY MR. JANUSH:

22 Q. Because --

23 A. -- of the algorithm.

24 Q. Because there's a risk that

1 if you don't have those elements in your
2 algorithm, those elements are possibly
3 being missed, right?

4 MR. BARKER: Object to form.

5 THE WITNESS: Not with our
6 current products, because we have
7 established customers that haven't
8 changed that much, and we know
9 what they're ordering. This
10 report was not just for
11 established products, but for this
12 product that just got approval
13 this year. And we will have more
14 customers, different distribution,
15 and more orders.

16 So he's saying, make sure
17 that we need to make these
18 changes.

19 BY MR. JANUSH:

20 Q. You bring up a really good
21 point. Thank you so much.

22 The point that you're
23 bringing up is, you had a one-dimensional
24 algorithm during the hottest years that

1 were you selling Duragesic and Nucynta;
2 isn't that right?

3 MR. BARKER: Object to form.

4 THE WITNESS: What were the
5 hottest years?

6 BY MR. JANUSH:

7 Q. Well, Nucynta came on the
8 market in 2009. Nucynta was divested, I
9 believe, in 2015 or '16.

10 A. When you mean the hottest
11 years --

12 Q. So meaning, when Terrance is
13 doing this review, it's already long
14 after Nucynta is gone, right?

15 MR. BARKER: Object to form.

16 THE WITNESS: Nucynta was
17 gone.

18 BY MR. JANUSH:

19 Q. And you had a
20 one-dimensional algorithm during the
21 entire time Nucynta was being sold,
22 right?

23 MR. BARKER: Object to form.

24 THE WITNESS: We had an

1 algorithm that looked at the
2 quantity that the customer -- the
3 historical ordering pattern.

4 BY MR. JANUSH:

5 Q. And that is a
6 one-dimensional algorithm, right?

7 MR. BARKER: Object to form.

8 THE WITNESS: The algorithm
9 had one factor.

10 BY MR. JANUSH:

11 Q. As you sit here today, and
12 after reading Terrance's report from the
13 Drug and Chemical Advisory Group, you're
14 not the least bit concerned that during
15 the years that you were selling the
16 opioid product, Nucynta, and during the
17 heavier years, before it became generic,
18 that you were selling and marketing
19 Duragesic, that you only had a
20 one-dimensional, one-factor algorithm?

21 MR. BARKER: Object to form.

22 THE WITNESS: If there was a
23 problem with our products, we
24 would have been called down as

1 part of the distributor
2 initiative.

3 BY MR. JANUSH:

4 Q. That's not what I asked you.

5 A. No. You're asking if we
6 were concerned. And that would mean, I
7 would be concerned if there was diversion
8 and abuse of our products. And if there
9 was, that was one of the criteria for the
10 distributor initiative. You were called
11 in, reviewed your SOM and your ARCOS
12 data.

13 Q. And two of the other
14 requirements of the C.F.R. at the very
15 same time as the distributor initiative
16 was ongoing concerned the fact that you
17 were to be measuring frequency as well as
18 ordering patterns, not just quantity;
19 isn't that right?

20 A. The C.F.R. says you need to
21 have a system in place. It does not say
22 your algorithm is the system.

23 Q. But if your algorithm isn't
24 measuring all three factors, you cannot

1 trigger for all three factors to be
2 reviewed. It would require a manual
3 review of every single order for you to
4 have a good system in the absence of
5 those two factors; isn't that right?

6 MR. BARKER: Object to form.

7 THE WITNESS: For Schedule
8 II orders, they are manually
9 entered. We get them on the same
10 days every week. The customer
11 service personnel know what the
12 customers typically order.

13 And when it goes in, the
14 algorithm would flag anything
15 suspicious, if the customer
16 service -- they're seeing every
17 Monday, Wednesday, from this
18 customer. This one only receives
19 once every 12 months.

20 BY MR. JANUSH:

21 Q. You're not saying customer
22 service is eyeballing every order and
23 manually checking every order, are you?

24 A. No. What I'm saying

1 overall, there is a program in place
2 where orders are looked at, and every
3 month we reviewed the orders that were
4 reviewed, put on, and we track how much
5 is going to all the customers based on
6 total controlled versus noncontrolled.

7 Q. But you weren't following
8 the C.F.R. --

9 A. The C.F.R. does not say your
10 algorithm needs to have all this.

11 Q. But your algorithm is what
12 triggers the review, right?

13 A. I'm saying we do other
14 reviews of all the other --

15 Q. You can't review an order
16 that wasn't tripped, correct? You can't
17 review it in realtime is what I'm saying?
18 If it's not tripped, it ships, right?

19 MR. BARKER: Object to form.

20 THE WITNESS: If it is not
21 typical of the ordering pattern
22 for the previous 12-month, 52-week
23 average, we --

24

1 BY MR. JANUSH:

2 Q. Ship it?

3 MR. BARKER: Object to form.

4 THE WITNESS: No. We
5 investigate.

6 BY MR. JANUSH:

7 Q. If it's -- if -- I'm saying
8 if you have an order and you're only
9 investigating an order on an algorithm
10 that measures quantity, you inherently
11 cannot trip that order via the algorithm
12 for frequency or for --

13 A. You can do pattern.

14 Q. -- pattern?

15 A. You can do pattern, because
16 if they don't order on a monthly basis
17 it's going to get flagged. That's a
18 pattern.

19 Q. When you say if they don't
20 order on a monthly basis. That's more
21 like when a SKU is not ordered over a
22 period of time, it trips?

23 A. So if a customer regularly
24 orders every month 100 each of a product,

1 that is their order. Their average is
2 going to be factored on that. So if they
3 deviate and all of the sudden orders 150,
4 it's going to flag it, that the quantity
5 is high, and then when we run the report,
6 we'll say, well, hey, why -- you've
7 always been getting 100 each. Why are
8 you asking 150 this month?

9 Q. Right. But that's a
10 quantity measurement. That's --

11 A. But that's also the pattern,
12 because the pattern takes in the
13 12 months, what they typically order, to
14 come up with the average.

15 Q. Right. The 12 months in
16 average, 150 is not going to be an
17 outlier on an average on -- if an order
18 is 100 for 12 months, you're going to
19 average that in, that's not going to be
20 a -- that's going to be a blip on the
21 radar, is what your example is.

22 A. I used the wrong number.
23 But if it -- if it was a significant
24 increase, it would have been.

1 Q. And then Terrance goes on to
2 say, going back to his recommendations,
3 "The algorithm would not detect multiple
4 customer orders during a given week. It
5 would not detect orders which consist of
6 gradual quantity increases of a
7 controlled substance over time."

8 Do you agree with his
9 position that the algorithm that you had
10 wouldn't have detected multiple customer
11 orders during a given week?

12 A. If we received multiple on
13 days that we weren't expecting.

14 Q. I'm not -- I'm not --

15 A. Because --

16 Q. -- allowing you to add --
17 add language on days that you were not
18 expecting. I'm talking about what he's
19 addressing.

20 He's addressing, "The
21 algorithm would not detect multiple
22 customer orders during a given week."

23 MR. BARKER: Object to form.

24

1 BY MR. JANUSH:

2 Q. Do you agree that the
3 algorithm would not have addressed
4 multiple customer orders during a given
5 week?

6 MR. BARKER: Object to form.

7 THE WITNESS: That is what
8 he wrote, and if they ordered it
9 continuously every single day, it
10 compares to the previous weeks.

11 BY MR. JANUSH:

12 Q. Or even multiple orders in a
13 week like I showed earlier with Cardinal,
14 right?

15 MS. BOODY: Object to form.

16 BY MR. JANUSH:

17 Q. It compares it to the
18 previous weeks, right?

19 MR. BARKER: Object to form.

20 THE WITNESS: That is
21 comparing to the previous weeks
22 average, the 52 weeks.

23 BY MR. JANUSH:

24 Q. So if Cardinal ordered every

1 three days a specific order, what
2 Terrance is saying is, your algorithm is
3 not detecting multiple customer orders
4 during a given week.

5 A. That is what he's saying.

6 Q. Do you disagree with it or
7 agree with it?

8 A. I don't know. Because I
9 would have to see somebody actually go --
10 we never had the case where somebody's
11 going in every single day to see what the
12 algorithm would do.

13 Q. And then he wrote, "It would
14 not detect orders which consist of
15 gradual quantity increases of a
16 controlled substance over time."

17 Do you see that?

18 A. Yes.

19 Q. Do you agree or disagree
20 with that statement?

21 A. I agree.

22 Q. And he wrote, "It would not
23 detect a new customer's orders for
24 controlled substances which initially

1 commence with larger than normal
2 quantities and remain at a constant
3 level."

4 Do you agree or disagree
5 with that recommendation?

6 A. If it was entered in
7 initially at a high level, yes.

8 Q. And he wrote that, "Your
9 algorithm does not distinguish between
10 controlled substances."

11 Do you agree that?

12 A. What do you think -- we
13 treat all of our control -- the
14 algorithm, we use it for -- no matter
15 what schedule, if it's an ADHD med or if
16 it's an opioid.

17 Q. I think that's his point,
18 that he's recommending that that be
19 modified. Isn't that his point?

20 MR. BARKER: Object to form.

21 THE WITNESS: I don't know
22 what he intended.

23 BY MR. JANUSH:

24 Q. Well, go up to Paragraph 4.

1 Isn't the purpose of Paragraph 4, above,
2 "Start modifying the existing SOM
3 algorithm and/or adding algorithms to
4 include additional evaluation criteria
5 for each specific DEA basic class of
6 controlled substance handled by J&J."

7 Isn't that going to this
8 concept of distinguishing between
9 controlled substances?

10 A. I misread this in thinking
11 that the algorithm doesn't do anything
12 different, no matter what the product is,
13 whether it's an opiate or a psychotropic.
14 And what he was saying is you should lump
15 in all the SKU -- all the total quantity
16 of the drug class and -- rather than the
17 SKU.

18 Q. Right. That's a critique on
19 his part, isn't it? I mean, I'm going to
20 find out. I'm going to be deposing him
21 one day. So I just want your opinion
22 whether he's critiquing Janssen or not on
23 this.

24 MR. BARKER: Object to form.

1 THE WITNESS: I don't know
2 what he means by that.

3 BY MR. JANUSH:

4 Q. Even when you look up at
5 Paragraph 4, you --

6 A. Well, I understand what he's
7 saying up here, that we should move from
8 the SKU to do an overall -- the drug
9 class of that product.

10 But down here, the algorithm
11 doesn't -- I don't know if he's saying,
12 you should do something different from
13 opiates versus ADHD. You shouldn't.
14 It's all a controlled substance.

15 Q. So let's talk about -- let's
16 talk about what he's saying in Paragraph
17 4.

18 Earlier, I was just
19 following along the lines of what JOM has
20 done. I was only looking at, on that
21 sales spreadsheet, the 100-milligram,
22 bottles of 100 pills, packed in 24
23 bottles per case.

24 Do you remember that?

1 A. Yes.

2 Q. I wasn't also adding in the
3 same day or same week orders for the
4 Nucynta 50 milligrams or the Nucynta
5 75 milligrams or the Nucynta
6 125 milligrams on top of Cardinal's
7 Nucynta 100-milligram orders.

8 You agree I was not doing
9 that, right?

10 MR. BARKER: Object to form.

11 MS. BOODY: Object to form.

12 THE WITNESS: You were just
13 highlighting the 100-milligram.

14 BY MR. JANUSH:

15 Q. Right. So there is a reason
16 I'm circling back to that, because what
17 Terrance was suggesting, was to move away
18 from the SKU to SKU, the same SKU
19 analysis, and lump in the total grams of
20 product and take into account all of the
21 Nucynta that would have been ordered by,
22 as an example, Cardinal, in a given week
23 or month, right?

24 A. Right.

1 Q. And there is a huge
2 difference between that suspicious order
3 monitoring analysis, and just going SKU
4 to SKU, isn't there?

5 MR. BARKER: Object to form.

6 THE WITNESS: It depends,
7 because when you come down to it,
8 and you just calculate how much
9 active ingredient is in a
10 50-milligram -- so there's
11 50 milligrams times 100 pills,
12 times whatever you mention, you're
13 going to come up with a different
14 historical ordering pattern.

15 And so you are not going to
16 have more flagged orders than we
17 currently have.

18 BY MR. JANUSH:

19 Q. Well, you're going to
20 have -- you're not going to have the
21 false positives on the company that
22 ordered a lot of the 100s of Nucynta but
23 may have only ordered a few of the 50s,
24 and then increases their orders of 50,

1 right? You're not going to have that get
2 flagged?

3 A. When they switch between
4 SKUs?

5 Q. Right?

6 A. Right.

7 Q. Am I correct?

8 A. Right.

9 Q. So Terrance is removing the
10 false positives and focusing on the
11 substantive issue of how much drug is a
12 company buying in a class, right?

13 A. How much of the active
14 ingredient the customer is ordering, yes.

15 Q. And yet, you still take the
16 position that he was not concerned about
17 whether JOM's system had, over the years,
18 missed suspicious orders?

19 A. No.

20 MR. JANUSH: I have no
21 further questions at this time.

22 MR. BARKER: Okay. Let's go
23 off the record. I just want to
24 talk to my colleague and see

1 whether I have any further
2 questions. But I don't think I
3 do.

4 THE VIDEOGRAPHER: The time
5 is 7:09 p.m. Off the record.

6 (Short break.)

7 THE VIDEOGRAPHER: The time
8 is 7:15 p.m. Back on the record.

9 MR. BARKER: Okay. Back on
10 the record. I have no further
11 questions, but I do have a request
12 in terms of reading and signing.

13 The usual stipulations
14 apply, except that the witness is
15 going to be out of town -- out of
16 the country for two weeks on
17 business. And so, therefore, we'd
18 like to have 45 days rather than
19 30.

20 MR. JANUSH: Agreed.

21 MR. BARKER: Thank you.
22 Nothing further.

23 MR. JANUSH: Thank you.

24 THE VIDEOGRAPHER: This

1 marks the end of today's
2 deposition. The time is 7:15 p.m.
3 Off the record.

4 (Excused.)

5 (Deposition concluded at
6 7:15 p.m.)

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1
2 CERTIFICATE
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4

5 I HEREBY CERTIFY that the
6 witness was duly sworn by me and that the
7 deposition is a true record of the
8 testimony given by the witness.

9 It was requested before
10 completion of the deposition that the
11 witness, MICHELE R. DEMPSEY , have the
12 opportunity to read and sign the
13 deposition transcript.

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12 MICHELLE L. GRAY,
13 A Registered Professional
14 Reporter, Certified Shorthand
15 Reporter, Certified Realtime
16 Reporter and Notary Public
17 Dated: March 13, 2019

18 (The foregoing certification
19 of this transcript does not apply to any
20 reproduction of the same by any means,
21 unless under the direct control and/or
22 supervision of the certifying reporter.)
23
24

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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4 PAGE LINE CHANGE

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2 ACKNOWLEDGMENT OF DEPONENT
3

4 I, _____, do
5 hereby certify that I have read the
6 foregoing pages, 412 - 825, and that the
7 same is a correct transcription of the
8 answers given by me to the questions
9 therein propounded, except for the
10 corrections or changes in form or
11 substance, if any, noted in the attached
12 Errata Sheet.
13
14
15

16 _____
MICHELE R. DEMPSEY

DATE

17
18
19 Subscribed and sworn
to before me this

20 _____ day of _____, 20____.

21 My commission expires: _____
22 _____

23 Notary Public
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